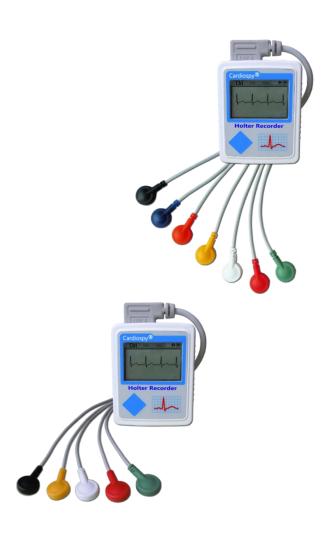
EC-2-3-12H Holter ECG System

Technical specification







TECHNICAL S	TECHNICAL SPECIFICATIONS OF DIFFERENT HOLTER SYSTEMS				
Type of Holter Recorders	EC-2H	EC-3H	EC-12H		
Bipolar ECG Channels	1, 2	1, 2, 3	1, 2, 3		
Other ECG Channels	-	+PM, Nehb	+PM Standard 12 CH, Nehb		
Respiration	-	Yes	Yes		
Number of snap type Leads	3, 5	3, 4, 5, 7	3, 4, 5, 7, 10		
Recording duration maximum (without battery changing)	48h	48h	24h		
The battery can be changed during recording		Yes			
Recording duration maximum (with battery changing)		336h			
Dynamic Bandwidth		±20 mV			
DC Offset Range		±600 mV			
Frequency Response maximum	0.05 Hz 150Hz				
Sampling Rate Recording Rate	125 Hz, 250 Hz, 500 Hz, 1000 Hz 125 Hz, 250 Hz, 500 Hz, 1000 Hz				
Common Mode Rejection Ratio	Ι.	23 Hz, 230 Hz, 300 Hz, 1000 120dB	П		
A/D Resolution		16 bit			
Input impedance		>100 MΩ			
•		1x1.2 V AAA NiMH			
Power Source		(or 1x1.5 V AAA alkaline)			
Battery Life	min. 24 h,	up to 48 h using a high-capa	acity battery		
Storage Card Capacity		built-in 8GB (microSD)	, ,		
Internal Voltage (max)		3.3 V			
Display	L	CD (Grey Scale 160x100 pixe	els)		
Movement detection-3D		Yes			
Patient Event button		Yes			
Monitoring ECG	On Po	C via Bluetooth and on LCD	as well		
Reading Record		via USB cable			
International Protection Rating Against Water: IPX0		Yes			
Size		53 x 67.5 x 18.5 mm			
Weight		~ 50 g			

Homepage: www.labtech.hu Email: medical@labtech.hu

Phone: +36-(52)-500-128 **Fax:** +36-(52)-500-129

BASIC FUNCTIONS OF SOFTWA	ARE					
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	Normal and MSI install	Full screen mode				
 HIS integrations: GDT, DICOM MODALITY WORKLIST, Cardiospy SDK 	Two display mode	Cubios HRV export				
FTP integration	Email function	AHA / IEC electrode placement				
	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	 Export ECG data to CSV, SCP, Dat format 				
Export QRS data	 Export N-N intervals 	Export R-R intervals				

HOLTER SOFTWARE FUNCTIONS						
 Make new record using PC or recorder display 	 Raw ECG visualization after reading to PC 	 Visualization of evaluated record on PC 				
 Store the Indication and medication of the patient 	Awake, Asleep and special time	 Smoothing, baseline, mains filters 				
Event Viewer	 Colour-coded event marking 	ST level/ST slope diagrams				
QT – QTc – QT% diagrams	QRS – PQ diagrams	 Atrial fibrillation and atrial flutter screen 				
Battery status	 Noise detection and editor 	 Lead off warnings 				
Detailed ECG Visualization	QRS Detection	 Adjustable parameters for analysis 				
HR and ST Graphs	 Arrhythmia Analysis (N,S,V) 	Full ECG Visualization				
 Measuring possibility on the ECG 	Insert and delete QRS	Rename QRS				
Mark noisy intervals	Delete single/group events	Patient event view				
Sleep apnea detection						

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Phone: +36-(52)-500-128 **Fax:** +36-(52)-500-129

ADDITIONAL FUNCTIONS OF DIFFERENT HOLTER SYSTEMS				
	EC-2H	EC-3H	EC-12H	
P-wave detection	+	+	+	
Motion Detection	+	+	+	
QRS Template Classification	+	+	+	
QT Analysis	+	+	+	
HRV Time Domain	+	+	+	
AV block I-II-III Analysis	+	+	+	
Atrial Fibrillation & Flutter Analyis		+	+	
HRV Frequency Domain		+	+	
Pacemaker Analysis		+	+	
Vector cardiography		+	+	
T Alternant			+	
HR Turbulence Analysis			+	
Respiration		+	+	

SOFTWARE MINIMU	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.

Homepage: www.labtech.hu
Email: medical@labtech.hu

Phone: +36-(52)-500-128 **Fax:** +36-(52)-500-129



ECG Holter System

Cardiospy® User Manual
For EC-2H; EC-3H; EC-12H; EC-3H/ABP recorder





LABTECH LTD.		
Address	4. Vág street Debrecen 4031 Hungary	
E-mail (technical support)	develop@labtech.hu	
E-mail (sales)	medical@labtech.hu	
Phone	+36-52-500-128	
Fax	+36-52-500-129	

LABTECH LTD. MADE IN HUNGARY

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 ECG Holter System!

Release date: 26-06-2012 Revision date: 17-01-2019 Version number: v6.6

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

LABTECH LTD.			
Address	4. Vág street Debrecen 4031 Hungary		
E-mail (technical support)	develop@labtech.hu		
E-mail (sales)	medical@labtech.hu		
Phone	+36-52-500-128		
Fax	+36-52-500-129		

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1 Introduction

Dear Customer!

Thank you for purchasing our Cardiospy ECG Holter System. We sincerely hope that our product will help you with your diagnostic and therapeutic work. To be able to use Holter System and computer programs appropriately, please read the manuals carefully. A basic knowledge of computers and Windows based applications are 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, even in person if need be.

What is a Holter?

A Holter is a non-invasive, long-term ambulatory ECG device that is capable of recording up to 24 (or even 48-72) hours of ECG signals.

How to use Holter monitoring?

The Holter recorder is worn by the patient for 24 hours, and records during normal daily activities, including sleep periods. After 24 hours, the readings are downloaded to a computer for analysis, where a qualified expert reviews and, if necessary, edits the data.

What is the main idea of Holter Monitoring?

Holter monitoring is a tool in the evaluation of patients with symptoms of various forms of heart disease, or in situations where the physician suspects cardiac pathology in the absence of symptoms. Holter monitoring is an ideal test because the patient assumes normal daily activities, increasing the likelihood that he or she will experience the precise situations that can trigger symptoms or cardiac events. This allows correlation of any rhythm problems or abnormalities with activities and/or symptoms. In the opposite sense, Holter monitoring can also be used to "rule out" cardiac causes of patients' symptoms.

2 Preparations for using the Holter System

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

2.1 List of accessories for EC-2H; EC-3H; EC-12H *

Please check the listed units and accessories before installing the ECG Holter System

Code No.	Specification	Qa.	EC- 2H	EC- 3H	EC- 12H	Picture
CAS- 00000-01	Case for holding the systems	1	х	х	х	
ACC- 0SWCD-01	CD with installation software	1	х	х	X	CARDIOSPY WESTER AND CONTROL OF THE PROPERTY
DEV- 0USBB-02	USB-02 Bluetooth interface unit	1	х	х	x	
DEV- 02HLC-05	EC-2H ECG Holter Recorder	1	х			Canoni
DEV- 03HLC-05	EC-3H ECG Holter Recorder	1		Х		Holter Recorder
DEV- 12HLC-05	EC-12H ECG Holter recorder	1			Х	

Code No.	Specification	Qa.	EC- 2H	EC- 3H	EC- 12H	Picture
BAG- 0012H-01	Recorder bag (EC-2-3-12H V5, attachable to patient's waistbelt)	1	X	х	X	
BAG- 0012H-02	Recorder bag (EC-2-3-12H V5, attachable to patient's neck)	1	X	X	X	Zamana *
CHA- 0002X-01	Battery charger MINI	1	х	X	X	A THOUSE AND A SECOND ASSESSMENT OF THE PARTY OF THE PART
BAT- 00000-01	1.2V Rechargeable batteries (AAA)	2	X	х	X	Energizer) ## F F F F F F F F F F F F F F F F F F
CAB- 00L02-06	2 CH bipolar patient cable (HDMI-Snap, 45cm)	1	х			

Code No.	Specification	Qa.	EC- 2H	EC- 3H	EC- 12H	Picture
CAB- 00L03-06	3 CH bipolar patient cable (HDMI-Snap, 45cm)	1		х		
CAB- 00L12-05	12 CH standard patient cable (HDMI-Snap connector)	1			х	
CAB- 00LNE-06	NEHB patient cable (HDMI- Snap, 45cm)	1			х	
CAB- 00USB-01	Extension cable for USB-02	1	X	х	х	
CAB- 00REC-05	Data transfer cable (USB A - HDMI)	1	Х	х	Х	
USR- 00000-01	Installation and Update Guide	1	х	х	х	A LABITED Installation and Explana Golds in the Conference of the

Code No.	Specification	Qa.	EC- 2H	EC- 3H	EC- 12H	Picture
USR- 00000-02	User manual for Holter recorders	1	Х	х	х	A LADERECH EST EMPLY STATEM EN CONTROL FOR THE STATEM EN CONTROL FOR T
ELE-00000- 01	Single-use electrodes (1 pack / 30 pcs)	1	X	X	X	0000

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

2.2 List of accessories for EC-3H/ABP

Code No.	Specification	Qa.	EC- 3H/ABP	Picture
CAS- 00ABP-01	Case for holding the recorder and accessories	1	Х	
ACC- 0SWCD- 01	CD with installation software	1	x	Cardiospy

^{*}The manufacturer reserves the right to change prices at any time.

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

Code No.	Specification	Qa.	EC- 3H/ABP	Picture
DEV- 0USBB-02	USB-02/B Bluetooth Interface Unit (monitoring and evaluation)	1	x	
DEV- 3HABP-05	EC-3H/ABP ECG and ABPM Recorder	1	X	
BAG- 3HABP-02	Recorder bag (EC-ABP V5, EC-3H/ABP V5, attachable to patient's waistbelt)	1	х	
CHA- 0004X-01	Battery charger MAXI	1	Х	
BAT- 00000-02	1.2V Rechargeable batteries (AA)	4	Х	Energizer & Section & Sect
CAB- 00L03-06	3 CH bipolar patient cable (HDMI-Snap, 45cm)	1	x	

Code No.	Specification	Qa.	EC- 3H/ABP	Picture
CAB- 00USB-01	Extension cable for USB-02	1	X	
CAB- 00REC-05	Data transfer cable (USB A - HDMI)	1	x	
USR- 00000-01	Installation and Update Guide	1	X	A LASTECH MANAGEMENT OF STATE THE STATE STATE OF STATE THE STATE
USR- 00000-02	User manual for Holter recorders	1	X	A LASTICAL SERVICE STATE OF THE SERVICE STATE OF T
ELE- 00000-01	Single-use electrodes (1 pack / 30 pcs)	1	х	
ELE- 00000-02	Single-use electrodes for cuff fixing	1	Х	, o c
BEL- 00000-01	Waist belt	1	х	

Code No.	Specification	Qa.	EC- 3H/ABP	Picture
CUF- 00LOC-31	BP cuff, Adult (23- 33cm)	1	X	Part Control of the state of th

^{*}The manufacturer reserves the right to change prices at any time.

Note: Please refer to the Code number above when placing an order.

2.3 Principles of Operation

Holter monitoring is a tool in the evaluation of patients with symptoms of various forms of heart disease, or in situations where the physician suspects cardiac pathology in the absence of symptoms. Symptoms such as lightheadedness, palpitations, or fainting may be caused by disturbances in the electrical signals that control the heart muscle contractions. These disturbances can be random, spontaneous, sleep-related, emotion- or stress-induced.

Holter monitoring is an ideal test because the patient assumes normal daily activities, increasing the likelihood that he or she will experience the precise situations that can trigger symptoms or cardiac events. This allows correlation of any rhythm problems or abnormalities with activities and/or symptoms. In the opposite sense, Holter monitoring can also be used to "rule out" cardiac causes of patients' symptoms.

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

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 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

2.4 Warnings and Contraindications of using Holter System



Never use the recorder:

- in wet conditions (the recorder is not waterproof)
- in strong heat
- in explosive surroundings
- in strong electrostatic field
- in the presence of flammable anaesthetics and oxygen rich environment.
- Do NOT remove recorder covers
- Do NOT immerse the recorder in any fluid
- the Holter is not defibrillator-protected, do not use with not-implanted defibrillator



Usage with other devices:

Holters may be used safely in patients with pacemakers, Implanted Cardiac Defibrillator (ICD) or other implanted devices. The implanted devices will not disrupt or be influenced by the operation of the recorder, as well as the recorder will not be influenced by the operation of the above devices.

The recorder may be used simultaneously with a high frequency surgical device, in this case make sure that the ECG electrodes are placed as far as possible away from the surgical field.

Do not use the recorder in MRI environment or in an excessive electromagnetic field.



Environmental conditions of storage and operation:

Temperature-range: -10-50°C

Relative humidity: 10-95% non-condensing

Air pressure-range: 700-1060 hPa

To achieve good and safe connection, to take care of the patient's skin and to avoid infection use only good quality single-use electrodes that are marked with the CE sign. Do not use electrodes with expired warranty or dry or used ones from old, previously opened packages because it will result in bad recording quality.

As in all Holter systems, noise and artefact may produce false positive ECG events. Therefore, patient data must be reviewed and edited by a qualified technician. You can find more information about evaluation in CHAPTER 4.2.4.

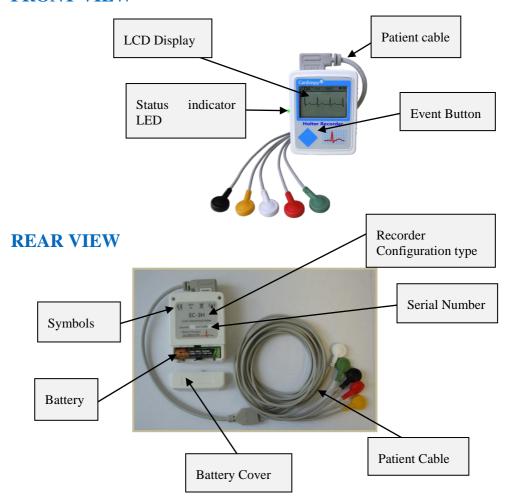
Opening the enclosure by unauthorized person may invalidate warranty. Modification of the ME equipment can only be performed by the manufacturer. In case of problems contact a professional repair shop.

NOTE: IF ANY ABNORMALITY OCCURS IN THE UNIT, SUSPEND THE OPERATION IMMEDIATELY AND DISCONNECT THE UNIT FROM THE PATIENT.

3 **Instructions for starting Holter Monitoring**

Main parts and functions of the Holter (EC-2H; EC-3H; EC-12H) 3.1

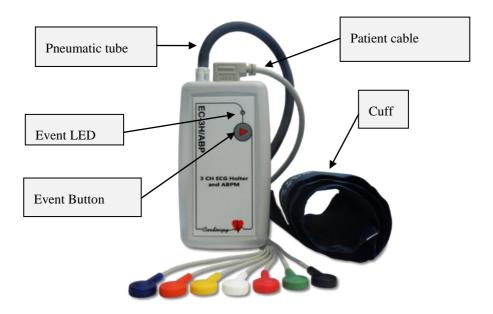
FRONT VIEW



ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

3.2 Main parts and functions of the Combined device

FRONT VIEW



3.2.1 Signs and alarms of EC-3H/ABP

The recorder contains a single RGB LED with which 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 it waits a few seconds and restarts automatically. If it's not then you should restart the recorder by replacing the batteries. If the problem still occurs it requires repairing.
The LED is red and flashing.	The battery has run out.	Battery exchange required.
The LED light is green.	The recorder connects to the PC through the USB data transfer cable and it works properly.	-
The green LED light flashes quickly.	The recorder connects to the PC through the USB data transfer cable and and there is data transfer between the PC and the recorder. The rythm of the flashing is syncronized with the rythm 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 successfully completed).	-

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

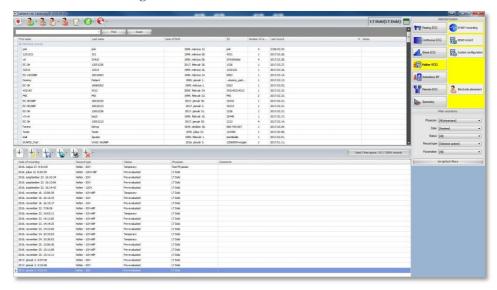
Light signal	Description	What should we do?
The yellow LED flashes.	The device is recording.	-
A crimson LED flashes	The recorder contains unread record.	You should read the last record from the recorder, otherwise you cannot start the next record and the device won't turn on the Bluetooth modul.
Blue LED seldom flashes	There is Bluetooth connection between the PC and recorder.	-
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 display the different statuses and errors.

Signal	Rhythm, tune	Status description
One high-pitched short beep	•	Push-button event on the recorder or on the PC (Start/Stop BP).
One short beep in deep voice	0	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.

Signal	Rhythm, tune	Status description
Two high-pitched short beep	••	Cannot start recording (no patient data).
		Push-button event, but there is no function related to pushing the Push-button in the current state of the recorder (for example: the recorder connects to the USB).
Two short beep in deep voice	00	The device was connected to USB.
Two short beep with rising melody	0•	Bluetooth connection was created.
Two short beep with descending melody	•0	Bluetooth connection was broken.
Three high-pitched short beep	•••	After the battery was put in the initialization, selftest 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.

If the patient has pacemaker, you can also select it's type here, with a short description. Besides, contact information and even notes can be entered.





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)

Since it is possible that a patient without pacemaker was examined with our system previously (has record in the database), but after that a pacemaker was implanted, you can modify the pacemaker type as well. In this case, the existing records will be kept without pacemaker detection, but new records will be analyzed with detecting pacemaker spikes. For more information, please read CHAPTER 5.5.5.



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".



DICOM Modality Worklist: The software gets in contact with the DICOM Modality Worklist and receives a list of the patients for whom examination is required. For more information about its settings, please check the **Cardiospy Installation and Update Guide**.

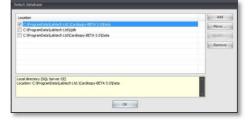
ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING



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

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.



new one.

so a of them The database

menu,

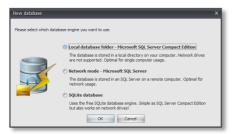
Clicking on the "Add" button creates a new database.

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.

There are three possible ways to create a database:

- 1. Local database
- Network mode Microsoft SQL Server
- 3. 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: The order of first and last name can be set in this menu.
- 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 do this, ask your local distributor and administrator.
- **Control Panel:** In this menu, you can find the general settings of the software. You can read more about it's option in the **Cardiospy Installation and Update Guide**.
- Date format: You can set the short and long form of system date here.
- 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 unticking the checkbox next to the name of it.



ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

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 is appearing 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 the current 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.

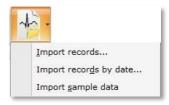


Load record: Opens the selected record from the list. Once the record is open we can edit, analyze or print it.

- **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.

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

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

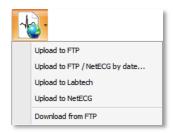
- FTP - upload and download:

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 FTP by date: You can upload records within a date interval.

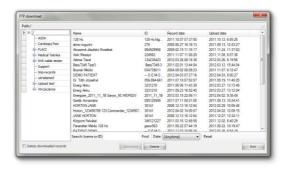
Upload to Labtech: In case you have any problem with the records, then you can upload them to the Labtech server.



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

Upload to NetECG: Here you can upload records to NetECG.

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.

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

3.5 How to start a new recording?

3.5.1 Patient preparation

3.5.1.1 Preparation for ECG measurement

Step 1: Place the case of the recorder unit on the right side of the patient and fix it on the belt on his/her waist. Although the case is washable, it is recommended to avoid skin-contact.



2. Shave excess body hair with razor on the electrode placement points.



3. Rub skin with abrasive prep pads for better contact.



4. Wipe surface of skin with alcohol pads and allow skin to dry.



5. Connect electrodes to the lead of the patient cable.



6. Attach electrodes to patient's body.

3.5.1.2 Preparation for BP measurement (EC-3H/ABP)

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.

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.

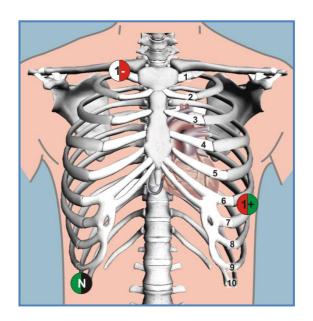
Do not remove the adhesive backing of the cuff anchor at this time.

NOTE: A NOISE-FREE RECORD CAN BE OBTAINED ONLY IF ALL THE STEPS OF PATIENT PREPARATION HAVE BEEN FOLLOWED ACCORDING TO THE INSTRUCTIONS. DO NOT START THE RECORDING IF ECG SIGN IS NOISY.

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

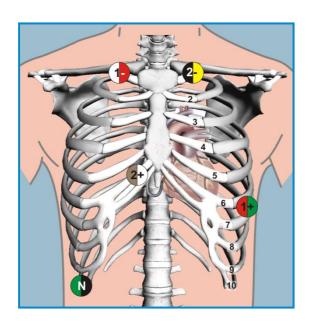
3.5.1.3 Electrode placement methods

3 lead placement (1 CH)



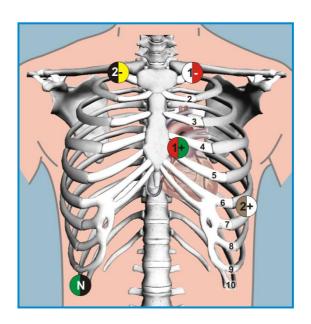
AHA Label	IEC Label	Electrode Placement
CH1+	СН1+	6th intercostal space at the anterior axillary's line
СН1-	CH1-	Right clavicle, lateral to the mid-clavicle line
RL	N	Lowest rib on right side of chest

5 lead placement (2 CH)



AHA Label	IEC Label	Electrode Placement
CH1+	CH1+	6th intercostal space at the anterior axillary's line
СН1-	CH1-	Right clavicle, lateral to the mid-clavicle line
CH2+	CH2+	Approximately 1 inch right of Xiphoid Process on the rib.
CH2-	CH2-	Left clavicle, lateral of sternum border
RL	N	Lowest rib on right side of chest

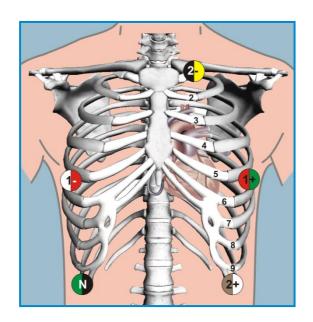
5 lead placement (2 CH)



AHA Label	IEC Label	Electrode Placement
CH1+	CH1+	4th intercostal space at left border of sternum
CH1-	CH1-	Left clavicle, lateral of sternum border
CH2+	CH2+	6th intercostal space at the anterior axillary's line
CH2-	CH2-	Right clavicle, lateral to the mid-clavicle line
RL	N	Lowest rib on right side of chest

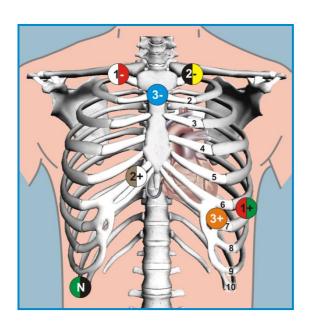
5 lead placement (2 CH)

Orthogonal



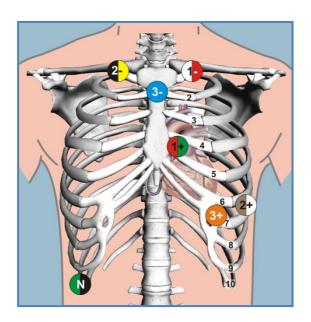
AHA Label	IEC Label	Electrode placement
CH1+	CH1+	5th intercostal space at the mid line of left axillary
CH1-	CH1-	5th intercostal space at the mid line of right axillary
CH2+	CH2+	Lowest rib on left side of chest
CH2-	CH2-	Left clavicle, lateral of sternum border
RL	N	Lowest rib on right side of chest

7 lead placement (3 CH)



AHA Label	IEC Label	Electrode Placement
CH1+	CH1+	6th intercostal space at the anterior axillary's line
СН1-	CH1-	Right clavicle, lateral to the mid-clavicle line
CH2+	CH2+	Approximately 1 inch right of Xiphoid Process on the rib.
CH2-	СН2-	Left clavicle, lateral of sternum border
CH3+	CH3+	6th intercostal space on left midclavicular line
СН3-	СН3-	Manubrium sternum
RL	N	Lowest rib on right side of chest

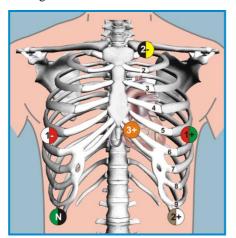
7 lead placement (3 CH)

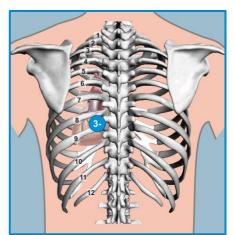


AHA Label	IEC Label	Electrode Placement
CH1+	CH1+	4th intercostal space at left border of sternum
CH1-	CH1-	Left clavicle, lateral of sternum border
CH2+	CH2+	6th intercostal space at the anterior axillary's line
CH2-	CH2-	Right clavicle, lateral to the mid-clavicle line
CH3+	CH3+	6th intercostal space on left midclavicular line
СН3-	СН3-	Manubrium sternum
RL	N	Lowest rib on right side of chest

7 lead placement (3 CH)

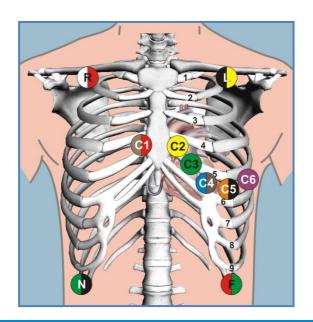
Orthogonal





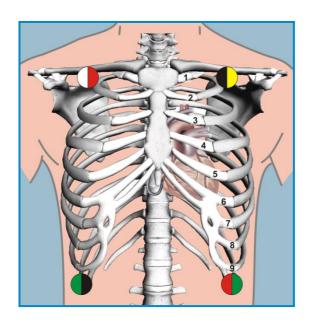
AHA Label	IEC Label	Electrode Placement
CH1+	CH1+	5th intercostal space at the mid line of left axillary
СН1-	CH1-	5th intercostal space at the mid line of right axillary
CH2+	CH2+	Lowest rib on the left side of chest
CH2-	CH2-	Left clavicle, lateral lateral of sternum border
СН3+	СН3+	Approximately 1 inch left of Xiphoid Process on the rib.
СН3-	СН3-	8th intercostal space at the center of the back, opposite the CH3+ electrode
RL	N	Lowest rib on right side of chest

10 lead placement (12 CH)



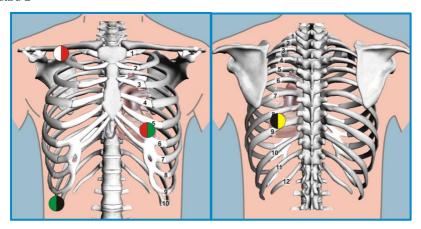
AHA Label	IEC Label	Electrode Placement
V1	C1	Fourth intercostal space at the right sternal border.
V2	C2	Fourth intercostal space at the left sternal border.
V3	C3	Midway between C4 and C2.
V4	C4	Mid-clavicular line in the fifth intercostal space.
V5	C5	Anterior axillary line on the same horizontal level as C4.
V6	C6	Mid-axillary line on the same horizontal level as C4 and
LA	L	Slightly below left clavicle.
RA	R	Slightly below the right clavicle
LL	F	Lower edge of the rib cage, or at the level of the
RL	N	umbilicus at the left and right mid-clavicular lines.

NEHB placement



AHA Label	IEC Label	Electrode Placement
		Slightly below left clavicle.
		Slightly below the right clavicle
		Lower edge of the rib cage, or at the level of the
		umbilicus at the left and right mid-clavicular lines.

NEHB placement



AHA Label	IEC Label	Electrode Placement
V1	C1	Nst – 2nd rib at the right sternal border
V2	C2	Nax - 5th intercostal space on the left posterior axillary line directly opposite (on the back,) from 3 (Nap)
V3	C3	Nap- 5th intercostal space mid-clavicular line (cardiac apex) equates to (V4 / C4)
RL	N	On the middle line of midaxillary, on the position of ribcage

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

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 <u>CHAPTER 3.6</u>. 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 monitor the quality of the ECG signal and start a test BP measurement if you have a combined (EC-3H/ABP) device, 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 monitor the quality of the ECG signal or 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 – start from the PC

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

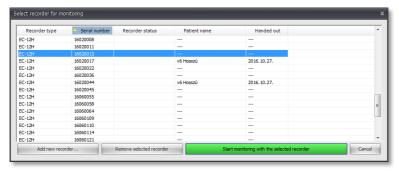
 Make sure the USB-02 dongle is connected to the PC and working properly.



- 2. Make sure the Holter ECG 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.
- At the Selected System / Holter ECG menu, click on "START recording".



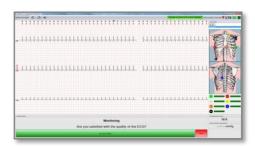
6. Select the device from the list with the proper serial number and then click on the "Start monitoring with the selected recorder" button.



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

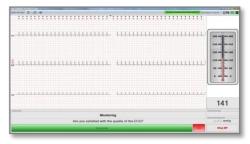
8. Check the quality of the ECG signals and make sure that the electrodes are properly attached to the patient and there is no lead-off on the illustration.

monitoring" button.



ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

 If you have a combined device, then you can start a test BP measurement by clicking on the "Start BP" button.



- 10. From this point, you can continue the process two ways:
- 11. Start the recording from the software:
- 12. If you are satisfied with the quality, you can start the recording by clicking on the "YES, START recording" button.
- 13. After you have started the recording successfully, a new window will pop up in which you can print the patient diary.
- 14. Check the display of the device. The following message should appear:





- 15. Start recording remotly from the device:
- 16. If you want to continue this way, then click on the "Cancel" button.
- 17. Hold the "Event button" on the recorder for 3 seconds to start recording.
- 18. Check the display of the device. The following message should appear:



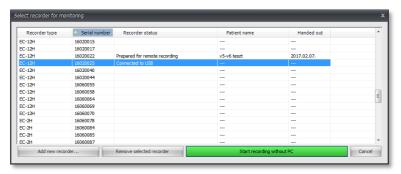
19. Please check CHAPTER 3.6 about how to read a record.

3.5.2.2 Start recording via USB cable

- 1. Make sure the Holter ECG 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 / Holter ECG menu, 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.
- After the successful programming, a new window will pop up in which you can print the patient diary.
- 8. Disconnect the device from the PC, connect the patient cable to it and then hold the "Event button" on the recorder for 3 seconds to start recording.
- Check the display of the device. The following message should appear:





10. Please check **CHAPTER 3.6** about how to read a record.

ECG HOLTER SYSTEM INSTRUCTIONS FOR STARTING HOLTER MONITORING

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 3.5.2.2 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. Connect the patient cable to the device and then hold the "Event button" on the recorder for 3 seconds to start recording.

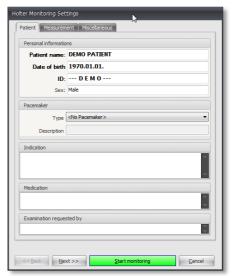


- 5. Check the display of the device. The following message should appear:
- 6. Please check CHAPTER 3.6 about how to read a record.

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 (enabled by default). You can manage the sound settings like Heart Rate beep and Lead-off signal. It is possible to set the length and frequency of the recording. For further information about the ECG filters, please check <u>CHAPTER 5.5.1</u>.

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 electrodes (and 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).
- 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 <u>CHAPTER 4.2.9.6</u>), an analyzing process will be performed.





6. Now you can start to examine and edit the record. See <u>CHAPTER 4</u>.

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 electrodes (and cuff) from him/her.
- 2. For faster reading process, please place fully charged batteries into the device before you connect it to the PC.
- 3. Start the Cardiospy program on the computer. Then select the Holter system.
- 4. Connect the recorder to the USB reader cable. The reading will start automatically (by default).

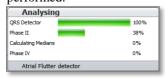
5. Since the recorder was started without prespecified patient data, thus you have to fill the personal data at the beginning of the reading process in a pop-up window.

Please theck the date and time of the record!

- Since the recording was started without any PC connection, you have to verify the date and time when the recording was started.
- 7. Click "Next" and then type the ID of the patient.
- 8. Click "Next" again and then fill the personal data of the patient.
- Click "Finish". A confirmation window will pop up.



- After the software finished with the reading, the "Record viewer" window will appear where you can analyze and evaluate the record.
- 11. If the automatic analyzing is enabled (see CHAPTER 4.2.9.6), an analyzing process will be performed.



12. Now you can start to examine and edit the record. See <u>CHAPTER 4</u>.



Date of recording: 2017.04.19, 12:25

Patient ID: TEST-ID-123

3.6.3 Patient data protection

From 25 May of 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.

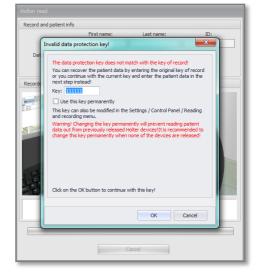


To sum the above, you can only recover the original patient data from a record, if you are using the same encoding key in your software (that same key which was used for starting the recording), otherwise, you will get a pop-up window, that your key is invalid and you will be prompted to enter the patient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

HOW TO READ A RECORD

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 Analyzing with the Cardiospy Software

4.1 Views

We can view the recorded ECG curve and its calculated parameters in many forms. The following chapter is dedicated to list these views in the order they appear in the software interface.

4.1.1 Main window

The "Main window" has three fields. "HR graph" (with BP and accelerometer values), "Trends" and the "ECG viewer". The graphs are colour-coded, which means that areas suspected to be pathological are highlighted in different colours.



4.1.1.1 *HR*, *BP*, *ACL graph*

The "HR graph" displays heart rate calculated from the ECG signal (for the definition of Avg. Hr see <u>CHAPTER 8.1.1</u>), motion intensity and in case the recorder comes with an integrated ABPM component, this graph shows blood pressure values as well.

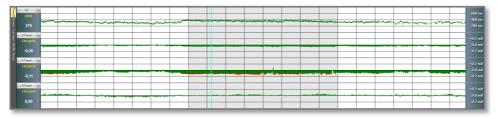
You can hide the values from the graph by clicking on the tabs at the left side. With the arrow below the tabs, you can hide the whole graph, giving more space to "Trends window" and the "ECG viewer". The heart rate graph is able to display the time distribution of events selected in **Events** menu. The temporal occurrence of individual events is indicated by small vertical lines.

Customization of the "HR graph" ranges is also available by clicking on the arrow below the tabs at the left side of the graph:

- 1. Off (hides the whole graph)
- 2. Default (0-250) ordinary enlargement
- 3. Optimized: enlarging the range between the minimum and maximum value
- 4. 50-150 range display
- 5. 50-200 range display

4.1.1.2 *Trends*

QT/ST



The algorithm can calculate ST and QT values from normal beats, bundle branch blocks (LBB, RBB, IVB) and pacemaker beats (aPMI, vPMI, dPMI, fPMI). You can set which type of beats should be included in the calculation in the **Settings/Parameters/ECG-ST/OT** menu.

The displayed value is calculated from the averages of beats within a ten-second range of the given ruler position. In case a section of ECG does not contain any of the selected beats from the settings, then ST is not calculated or displayed. The ST level is calculated from the J+ point (see **Settings / Parameters / ECG-ST/QT**). We can also edit QT, QTc and ST values in the software.

For further information about the Parameters menu, please check <u>CHAPTER 5</u>.



The scaling of the ST chart (the ST levels) can be changed with the zoom button found on the toolbar. If the ST level does not fit into the 1X range then you can set it to 0,5X range, and if the ST levels are too small you can set it to 2X range to zoom in.

You can also change the J+ point parameter on the toolbar.

For information about the editing possibilities, please check **CHAPTER 6.4**.

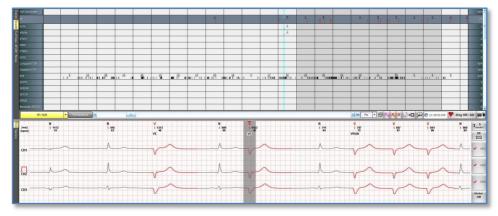
4.1.1.3 *Events*

By selecting **Events** from the tabs on the left side, we can see a summary containing events of the entire record.

The graph has three columns:

- 1. the left column contains Event types,
- 2. the middle column displays their time distribution
- 3. the column on the right side shows the aggregate number of each event.

"Single" or "group" type of events can be selected by clicking on them.



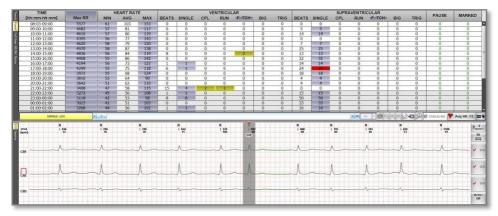
You can edit the list of events. Under the menu of "Settings" / "Events", see more in CHAPTER 4.2.9.3.

If you select an event type by clicking on its row in the table, then you can move between its elements with the slidebar or with the arrow ($\leftarrow \rightarrow$) buttons on the keyboard. Editing – CHAPTER 6.2.

You can only do this if the event that you have selected is not an "interval type" event. The "interval type" events are showed in % value (e.g. Atrial fibrillation, Atrial flutter, AV I, AV II, etc.). To edit these event types, please check <u>CHAPTER 6.2.10</u>.

Atrial flutter and fibrillation events are not available for EC-2H devices!





This function is completely like a summary table, but here you can jump to the highlighted events.

The "event cells" that are highlighted with grey background include all the events within the time interval that you can see in the first column.

The "event cells" that are highlighted with yellow background show the Min and Max HR in the Heart Rate column. In the Ventricular and Supraventricular columns, the event cells are also highlighted with yellow background where the most events happened in the whole record (time interval) from the same type of event.

The selected / used "event cells" are highlighted with red background.

In the main row, as you can see, the cell of the Tachycardia is also highlighted with grey background. That is because you can switch between the Longest and Fastest Tachycardia.

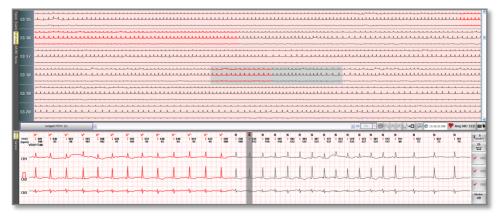
If you select an event type by clicking on a highlighted cell, then you can move between its elements with the slidebar or with the arrow $(\leftarrow \rightarrow)$ buttons on the keyboard.

4.1.1.4 Full View

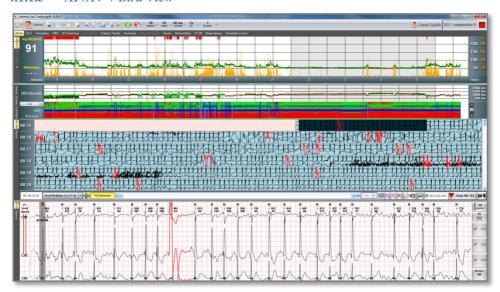
In this menu we can overview a longer section of the ECG curve. The window displays the number of ECG channels selected in the "ECG viewer". The selected ECG interval changes with the settings of the ECG paper speed.

The "ECG viewer" in the lower section displays the sub-section which we select in the "Full View" by left-clicking with the mouse.

You can see a longer section of the ECG on your screen with turning off from the channels (1 must be enabled) or if you disable the "HR graph" at the top of the screen.

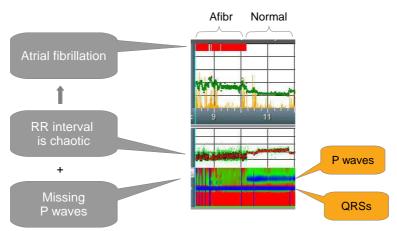


4.1.1.5 AF/AV + Bird View



This tab displays the graph of NN Intervals, which helps us checking the correct detection of Atrial Fibrillation, Atrial Flutter, AV I, AV II M1, AV II M2 and AV III events. There is also another graph called **Bird View**.

This function makes detecting Atrial Fibrillation very easy and very quick.



ECG HOLTER SYSTEM

ANALYZING WITH THE CARDIOSPY SOFTWARE

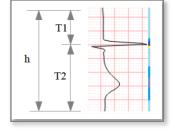
This Bird View graph is formed based on the amplitude of the periods before (T1) and after (T2) the QRS with colors.

Meaning of colors:

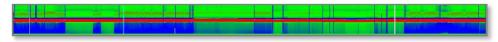
Blue: positive amplitude

Green: amplitude is around zero

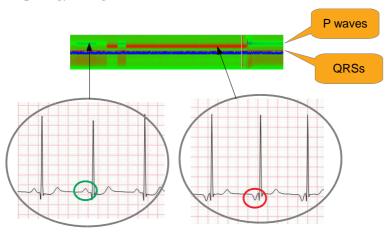
Red: negative amplitude



On the below picture, you can see ST elevation. Where the Bird View is bluer after the QRS, it means ST elevation. Where it is greener, it means the ST is normal.



P wave morphology change:

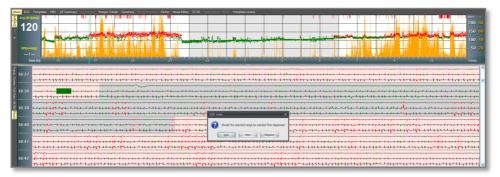


For further information about editing these events, please check <u>CHAPTER 6.2.10</u>.

4.1.1.6 *Noise*

The significance of this function is that it enables us to mark any section as noise, either from the "HR graph" or the "ECG viewer". However, sections of noise can also be marked as normal in this function. Apart from this, the intervals marked as noise by the software's automatic noise detector are indicated by a different background colour.

For further information about the editing possibilities, go to **CHAPTER 6.6**.



4.1.1.7 ECG viewer

The "ECG viewer" displays the selected channels in the desired size. Clicking on the "Median" button in the lower left corner displays the median that belongs to the selected ECG section. Both the median and the ECG curve can be measured in terms of time and amplitude. Editing is enabled in the "ECG viewer" (e.g., insert, delete or classify QRS).



For further information about the editing possibilities, go to CHAPTER 6.2.

4.1.1.8 *Service*

The Service field illustrates the technical details of the device. It displays the lead-off events of each electrode, and the state of battery. Here, you can see the firmware version of the recorder, the quality of the record, and the end point criteria.

4.1.2 ECG viewer – large window

The ECG tab displays the ECG curve in a larger size. You can also view the ECG channels in two columns and you can edit beats in the "ECG viewer" (e.g., insert, delete or classify QRS.).

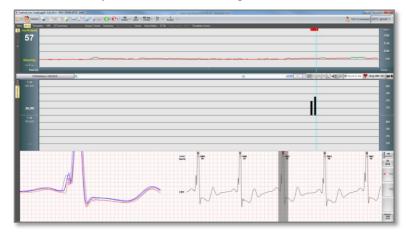


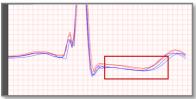
For further information about the editing possibilities, go to CHAPTER 6.2.

4.1.2.1 *T-alternans*

This feature is not available for EC-2H and EC-3H devices!

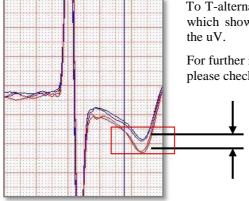
The term alternans applies to conditions characterized by the sudden appearance of a periodic beat-to-beat change in some aspect of cardiac electrical or mechanical behavior. You can clearly see it on the below two photos.





In the HR field the time interval is marked with red line, where the SW detected T-alternans. The detection is completed for each Holter channel, so that is why the event line belongs to that channel, which was chosen in the "ECG viewer".

The meaning of the amplitude of alternans:



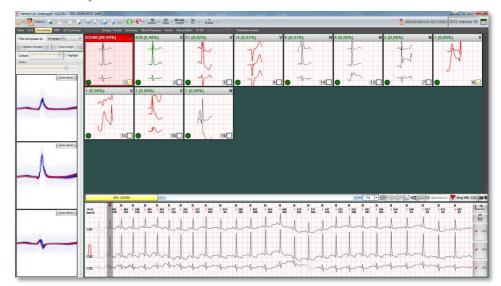
To T-alternans events the amplitude belongs as well, which shows the amplitude size of the alternans in the uV.

For further information about the editing possibilities, please check CHAPTER 6.5.

$$X [uV] A = \frac{X}{2}.$$

On the picture the QRS with even indexes are marked with blue, the odd ones are marked with red

4.1.3 Templates

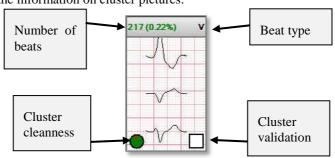




The analysis software classifies each heartbeat (N, S, V) and clusters similar formations.

Filter templates by function in the upper left corner serves to display QRS complexes of different types altogether or individually.

Meaning of the information on cluster pictures:



Cluster cleanness measuring circle (homogeneity)



Somewhat mixed cluster

If a cluster is marked with green circle, it means that the QRS complexes belong to the cluster show very similar forms to the cluster QRS shape. The red area in a circle signifies the percentage of non-similar QRS shapes.

The validation of a type of cluster means the affirmation of the type. If you click on a template the program automatically puts a yellow check mark as a default setting. This is good to see in which template you have already been. You can switch off the automatic check mark under the menu of Settings (Automatic check mark, choosing form). If you want to confirm the automatic checking you can click on the yellow check mark which will turn green as proof of that the template has been searched thoroughly.

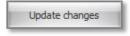
Not validated type.



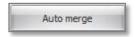
Automatic marking



Validated type by user

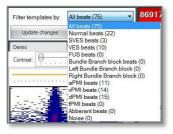


With the "Update changes" function, the software will reorder the clusters by the size of them (number of elements).



With the "Automerge" function, the software will automatically recognize the same beat types with similar forms and then it is merging them into the right clusters (it

even create new ones if it is necessary).



You can filter the templates by beat types.

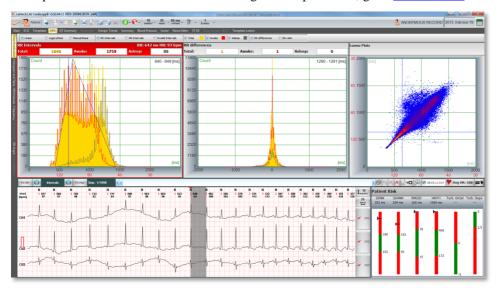
Please check **CHAPTER 6.1** for more detailed information about the functions.

4.1.4 HRV window

The HRV window provides detailed information on time and frequency parameters of RR variability.

4.1.4.1 Time Distribution

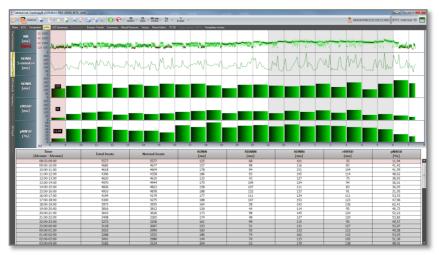
Three graphs are displayed in this section: RR Intervals, RR Differences and Lorenz plots. We can also edit data in the RR Intervals graph, for example we can validate or revalidate the intervals (see CHAPTER 6.3). Data edition is convenient, because the ECG pertaining to each selected interval is displayed immediately in a lower section. Next to the ECG-display we can see the Patient Risk graph, which is calculated from the HRV parameters. To check the exact meaning of each parameter, go to CHAPTER 8.



To check data edition possibilities, go to **CHAPTER 6.3**.

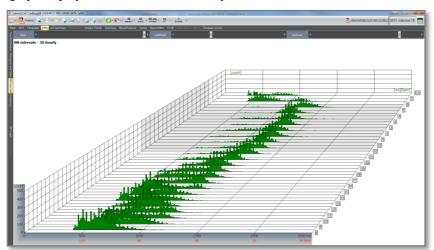
4.1.4.2 Histogram and Table

The first row of this graph displays SDNN values by a 5-minute division, the second one contains SDNN calculated for 1 hour, the last two rows contain rMSSD and PNN50% values. In the lower part of the screen we can see these values in table format.



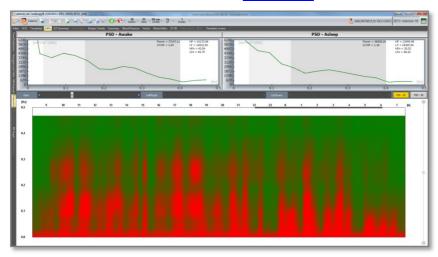
4.1.4.3 *NN Intervals*

This graph displays NN intervals in an hourly division in 3D.



4.1.4.4 Frequency

In the representation of frequency range, three graphs are displayed: one showing the period when the patient is awake, one when he/she is asleep and one for the total period of the measurement time, represented in a 3D HRV frequency graph. The latter can be represented in a 2D format as well. Parameters: CHAPTER 8.



4.1.4.5 *RR Graphs*

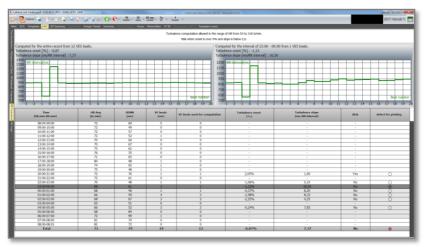
Here you can see the RR Max and Min ECG views and the diagram shows the distribution of the RR intervals.



4.1.4.6 HR Turbulence

This feature is not available for EC-2H and EC-3H devices!

This menu point displays the HR turbulence both in graph and table formats.



For more info about its calculation, see **CHAPTER 8**.

4.1.5 QT Summary window

The values of the QT analysis are shown in the form of a distribution graph and a table. We can choose to display QT or QTc values by selecting one of them at the left side of the distribution graph, while the table displays both values.

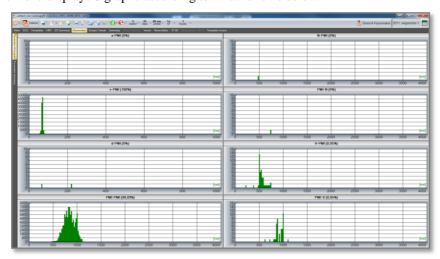


4.1.6 Pacemaker

This feature is not available for EC-2H devices!

4.1.6.1 Pacemaker Histograms

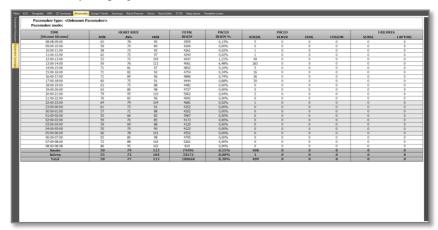
This menu displays 8 graphs according to what follows below:



a-PMI	The time distribution between the stimulation of the atrium and the heart beat (induced by the heart on this stimulation).						
v-PMI	The time distribution between the stimulation of the ventricle and the heart beat (induced by the heart on this stimulation).						
d-PMI	The time distribution between the stimulation of the atrium and the ventricle and the heart beat (induced by the heart on this stimulation).						
N-PMI	The distribution graph of the normal and PM induced beats.						
V-PMI	The distribution graph of the ventricular and PM induced beats.						
PMI-N	The distribution graph of the PM induced and normal beats.						
PMI-V	The distribution graph of the PM induced and ventricular beats.						
PMI-PMI	The distribution graph of consecutive PM induced beats.						

4.1.6.2 Pacemaker Summary

Here you can view a table summary of the pacemaker analysis. The number of beats induced by the PM is presented in the table in groups based on the type of the induction in an hourly division. The table shows the failure of electric capture and failure to sense events detected by the program as well.



The failure to capture (FTC) means that the pacemaker spike appears at the right time, but it is not followed by QRS. The failure to sense (FTS) refers to premature pacemaker stimulation, in which case the pacemaker produces a stimulus, without being stimulated by the patient's heart.

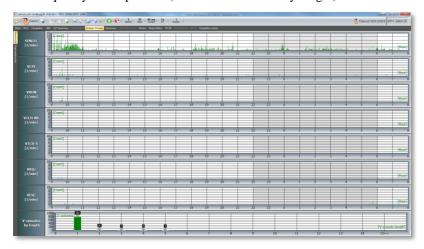
The possible pacemaker beat types are the following:

- aPMI: The atrium is paced, there is one pacemaker spike found before the P wave.
- vPMI: The ventricum is paced, there is one pacemaker spike found before the QRS.
- **dPMI**: Dual paced QRS, both the atrium and ventricum are paced. There are two pacemaker spikes found before the QRS.
- **fPMI:** Fusion beat. Spike is found on the QRS.

4.1.7 Ectopic Trends

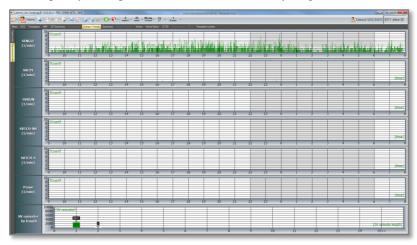
4.1.7.1 Ventricular

Represents the frequency of events related to V beats on the time axis. The last graph shows the frequency of V episodes (consecutive V beats by length).



4.1.7.2 SupraVentricular

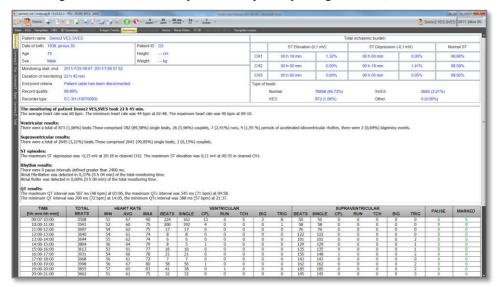
Represents the frequency of events related to S beats on the time axis. The last graph shows the frequency of S episodes (consecutive S beats by length).

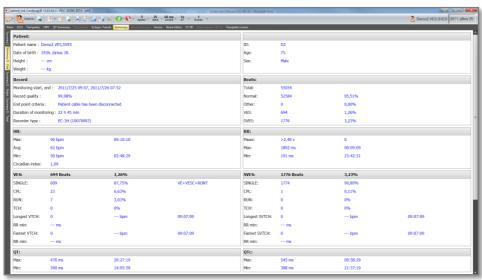


For more information, please check <u>CHAPTER 5.2.2</u> and <u>CHAPTER 8</u>.

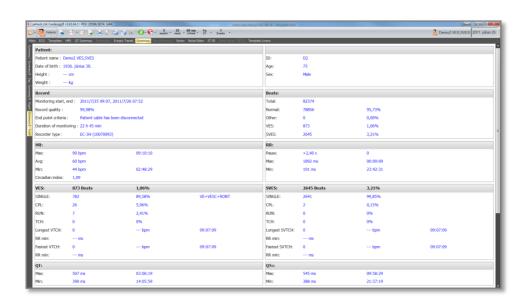
4.1.8 Summary window

This menu displays the most important findings in the automatic summary of the monitoring in 4 formats (Summary I, Summary II Day, - Night, - Total).





	03.04.11 (REV: 20596) BETA (H64)	Ø № Ø · € · · · · · · · · · · · · · · · · ·		Name and Add Street Add Street			A Demo2 VES,SVES 2011	
	N QT Summary Pacemaker Ect		Vector Noise Editor ST 3D Steep Apriles - DETA	Templete-Lorenz			5 Deliloz VE3,3VE3 2011	. junu
Patient:								
Patient name : Der	no2 VES.SVES			ID:	D2			
Date of birth: 193	36. június 30.			Age:	75			
Height: cm					Male			
Weight:	kg							
Record				Beats:				
Monitoring start, e	nd: 2011/7/25 09:07, 20	11/7/26 07:52		Total:	27320			
Record quality: 99,58% End point criteria: Patient cable has been disconnected Ouration of monitoring: 22 h 45 min					26272	96,16%		
					0	0,00%		
					179	0,66%		
Recorder type :	EC-3H (10070093)			SVES:	869	3,18%		
HR:				RR:				
Max:	85 bpm	09:10:10		Pause:	>2,40 s	0		
Avg:	57 bpm			Max:	1892 ms	00:09:09		
Min:	44 bpm	02:48:29		Min:	191 ms	23:42:31		
Circadian index:	1,09							
VES:	179 Beats	0,66%		SVES:	869 Beats	3,18%		
SINGLE:	173	96,65%	VE+VESC+RONT	SINGLE:	867	99,77%		
CPL:	3	3,35%		CPL:	1	0,23%		
RUN:	0	0%		RUN:	0	0%		
TCH:	0	0%		TCH:	0	0%		
Longest VTCH:	0	bpm	09:07:09	Longest SVTCH:	0	bpm	09:07:09	
RR min:	ms			RR min:	ms			
Fastest VTCH:	0	bpm	09:07:09	Fastest SVTCH:	0	bpm	09:07:09	
RR min:	ms			RR min:	ms			
QT:				QTc:				
Max:	507 ms	03:06:19		Max:	528 ms	22:11:39		
Min:	414 ms	22:18:39		Min:	388 ms	02:08:29		



4.1.9 Blood Pressure (EC-3H/ABP)

4.1.9.1 *HR*, *BP graph*

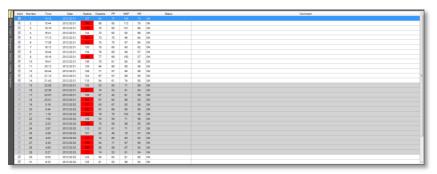
The graph presents Heart Rate and Blood Pressure measured by the ABPM device.



4.1.9.2 Table

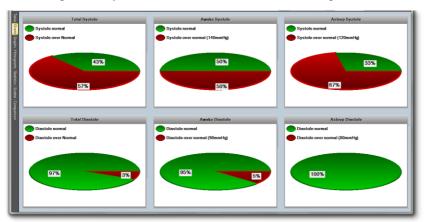
The table displays all the BP results in a chronological order. We can validate / invalidate each result by ticking / un-ticking the relevant checkbox in the column marked "Valid".

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



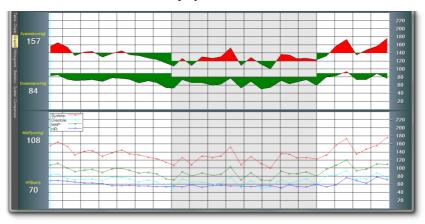
4.1.9.3 *Charts*

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



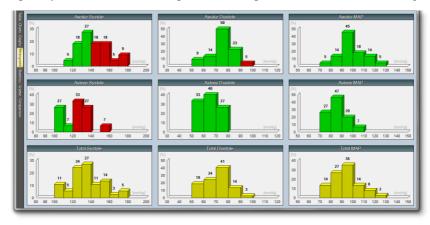
4.1.9.4 *Graphs*

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



4.1.9.5 Histograms

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



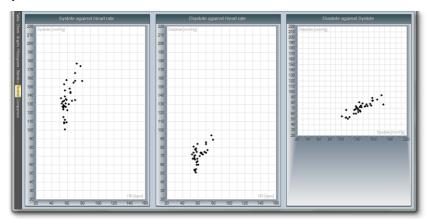
4.1.9.6 *Statistics*

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

	Total (Rendings: 37, Invalid: 0)					Analo Special Awake (Readings: 22, Invalid: 0)					
		Min	Avg	Max	SD		Min	Avg	Max	SD	
	Systole [mmHq]	101	135	177	20.0	Systole [mmHg]	115	143	177	18,0	
	Systole [mmrlg]	101	135	1//	20,0	Diastole [mmHg]	54	75	94	10,0	
hs Histograms S	Diastole [mmHg]	51	70	94	12,0	HR [bpm]	54	63	79	8,0	
	HR [bpm]	52	60	79	8.0	MAP [mmHg]	74	97	120	12,0	
Stati:	rik (opin)	52	00	/3	0,0	Pulse Pressure [mmHg]	52	68	100	12,0	
tics	MAP [mmHg]	70	92	120	14,0	Double Product	6210	9009	13983	151,0	
	Pulse Pressure [mmHg]	42 64		100	12.0	Systole over Normal	50 %				
	Pulse Plessure (mining)	42	04	100	12,0	Diastole over Normal	5 %				
	Double Product	5252	8100	13983	154,0	Hyperbaric Impact Systole	108				
	Systole over Normal	57 %				Hyperbaric Impact Diastole 3					
	Diastole over Normal	3%				Asleep (Readings: 15, Invalid: 0)					
						Min	Avg	Max	SD		
	Hyperbaric Impact Systole	3				Systole [mmHg]	101	124	153	15.0	
	Hyperbaric Impact Diastole					Diastole [mmHg]	51	64	78	9.0	
						HR [bpm]	52	55	59	2.0	
	AASI	1,00			MAP [mmHg]	70	84	103	11.0		
	Diurnal Index Systole	13,29 %				Pulse Pressure [mmHg]	42	59	75	10.0	
	Diurnal Index Diastole	14,67 %			Double Product	5252	6820	9027	35.0		
	Diurnal Index Diastole				Systole over Normal	67 %					
	Dipper Status	Dipper				Diastole over Normal	0 %				
	Morning Surge (mmHg) 28			Hyperbaric Impact Systole	83						
	Morning Surge [mmHg] 28			Hyperbaric Impact Diastole	perbaric Impact Diastole 0						

4.1.9.7 *Scatter*

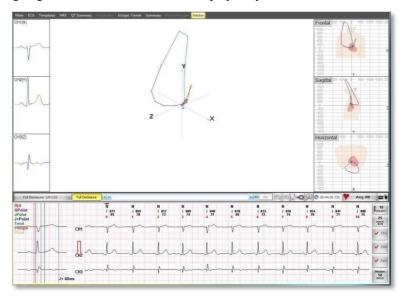
In this function, the cohesive systole-HR, diastole-HR and Systole-Diastole points are displayed.



4.1.10 Vectorcardiography

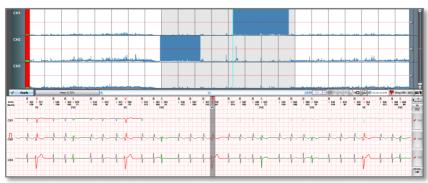
This feature is not available for EC-2H devices!

The Vectorcardiographic display mode is available with records made with EC-3H or EC12H recorders using 3-channel patient cables in orthogonal electrode placement. The medians of the ECGs are displayed in 2D and 3D coordinate systems. Their display is colour-coded which makes it easy to keep track of the QRS in the vectorcardiogram. The assigning of ECG channels to axes is displayed by the software.



4.1.11 Noise Editor

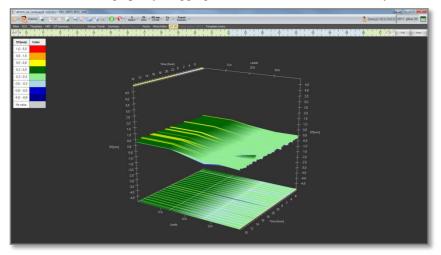
This function gives you the opportunity to mark a selected interval as noise per channels separately! For further information about the editing, check CHAPTER 6.6.2.



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4.1.12 ST 3D

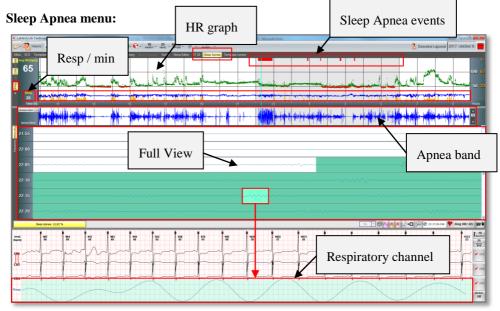
In this menu, you can see the ST level values in a 3D graph. The three parameters of the chart are: Time (h), Leads (separately), ST level (mm). You can set the graph to view the ST level for the full time or divided into hours. On the time scale, you can go to any time to view the ST level in a 1 hour interval by dragging the left mouse button on it. You can also rotate the graph by dragging the left mouse button on it to any direction.



4.1.13 Sleep Apnea

We have implemented a new function - Sleep Apnea - into Cardiospy, which allows the user to examine respiratory signals.

This function is only available for EC-3H, EC-12H and EC-3H/ABP devices. These devices can be used with any supported patient cable to be able to take the advantages of this new function.



This respiration channel shows the selected section of respiration in the Full view menu in a zoomed version.

4.1.13.1 Sleep Apnea components

- 1. "Resp." tab at HR graph: You can turn on / off respiration on the HR graph.
- 2. Full respiration on HR graph:

The blue element of the HR graph shows the full respiration signal hourly for the whole record.

3. Sleep Apnea events:

You can see the Sleep Apnea events marked with red on the HR graph.



4. Resp / min:

It displays the number of breaths per minute (20/min).-



5. Sleep Apnea band:



Here you can see the Apnea frequency band, where you can also measure the time period of Apnea. With the combo box at the left side, you can select which method you would like to use to analyze the respiratory signal. You can adjust the amplitude of Apnea band with the scrollbar at the right side.

<u>In V6 recorders, there is a separate channel that is used for recording respiratory signals,</u> which can be selected in this menu ("Respiration").

However, Cardiospy is also able to generate respiratory signals from chest impedance or from QRS amplitudes. You can select this method by selecting the other channels.

This method makes the previous type of recorders (V5 Holter, and EC-3H/ABP) able to calculate respiratory signals from ECG.

6. Sleep Apnea – Full view

Here, you can see the full view of respiration per 5 minutes of data in each row.

In daytime, the patient moves a lot. Therefore, the respiration is not consistent. Since it is impossible to measure and detect respiratory malfunctions in this time period, Sleep Apnea is only detected in the night time of the days, when the patient rests (sleeping).

How respiration looks like in night time when Sleep Apnea is detected:

Respiratory signals are highlighted with blue background where Apnea events are detected by Cardiospy algorithm.

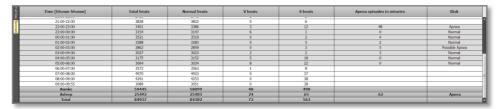
Beginning of Sleep Apnea event



The difference is clearly visible. The patient has started to breath less and less, then he /she started "gasping for breath" (took big breath).

7. Respiratory channel (under ECG channels)

4.1.13.2 Sleep Apnea - Summary table



This menu shows a summary about the result of the Sleep Apnea algorithm.

Hourly Risk ratings of the Sleep Apnea algorithm:

- Apnea, if in that given hour -, the number of minutes where Apnea is detected is more than or equal with 15.
- Possible Apnea if in that given hour -, the number of minutes where Apnea is detected is more than or equal with 5, but less than 15.
- Normal, in every other cases.

Ratings of the Asleep summary in the table:

In the night period, if the number of minutes where Apnea is detected - calculated in percent - is more than 5% and

- at least 1 hour is rated as Apnea
- if not rated as Apnea, but at least 1 hour is rated as Possible Apnea

Normal, in every other cases.

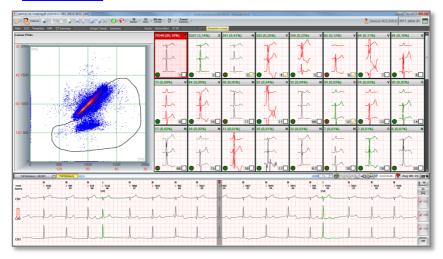
4.1.13.3 Modifying Sleep Apnea events

Since Sleep Apnea is only detected in night time of the days, it is recommended to adjust this period correctly. Please, read CHAPTER 5.1 for more information about how to set time periods.

You can read about the editing possibilities of Sleep Apnea events at CHAPTER 6.7.

4.1.14 Template-Lorenz

Here, you can demix the templates manually on a graphic interface. To see how, please check CHAPTER 6.8.



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 are able to export data into ".txt" file like QRS data, N-N intervals and R-R intervals.

4.2.1.1 Export wizard:



This function guides you through the exporting process, where you can also select all of the above options.

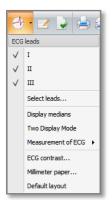
The mostly used exportable data is the "ECG data". You can export it in 3 possible extensions: CSV, SCP and DAT. You can export both RAW and Filtered ECG as well. At the end

of the export wizard, you can edit the name of the file and the path where you wish to export it.

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

Patients

4.2.2 ECG leads



In this menu, you can set which channels you want to see. This menu controls the visibility of the channels in menus where only 3 channels are visible. It does not control the "ECG" menu.

4.2.2.1 Select leads...

You can enable (only) 3 channels in a new window. This menu is recommended to use if you are using 12 channel.

There is another option in the ECG view (at the right-bottom part of the screen), where you are able to manage the visibility of the channels (even more quickly).

If you move the cursor above the button, then

a new list will appear, where you can choose which channel you want to see. You can do it with the other two channels as well.

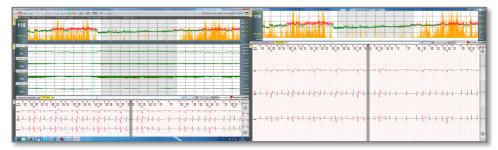
4.2.2.2 Display medians

You can enable / disable the medians in the ECG view with this menu point. You can also do it by clicking on the "Median" button.



4.2.2.3 Two display mode

Since it is recommended to use two displays (monitors) with the PC, you are able to use the software in "two display mode", when you analyze a record.



In the secondary window, the ECG (large window) menu will be showed.

4.2.2.4 Measurement of ECG

Here you can choose what kind of unit you want to use for the ST level values. (mm, mV or μV).

4.2.2.5 *ECG contrast...*

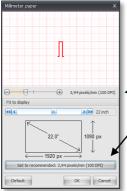


In this menu, you can change the contrast of the ECG-curve lines.

As you can see on the picture, you can even set it by events separately.

By default, the VES and SVES events are thickened to make them more visible

4.2.2.6 *Millimeter paper...*



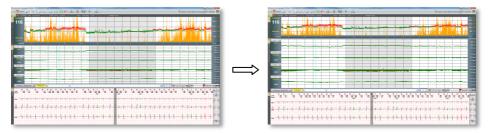
This window is active in stress and Holter system, by clicking view menu, Millimetre paper menu. Adjustment of millimetre paper size correlating to the monitor is possible. It is possible to setup real, 1:1 scale appearance of the millimetre paper on screen.

←You can manually set how many pixels match for 1 mm.

You can also use the "Set to recommended" button, so the software will automatically set the scale to 1:1.

4.2.2.7 Default layout

If you change the size of the windows inside the software, you can reset them back to the default sizes by this menu point.



4.2.3 Report



By selecting the Report menu, a text editor appears in which you can write remarks. By selecting the "Import report" / "Automatic report" menu, 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.

You can create your own templates by selecting the "Import report" / "Create a new template" menu. These templates can be imported later. Here you can insert many variables.

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

4.2.4 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 finished evaluating a section (like QRS templates, RR intervals, HR, QT, etc.), then you can tick the checkboxes next to the name of the sections separately.

It is suggested to check the longer (> 1000 ms) invalid RR intervals as well. In case of a noisy record it can happen that a real Pause gets among the invalid intervals. (An invalid RR interval can be made valid as it is written in CHAPTER 4.1.4.1)

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. The status of the record will turn into "Approved" at the database screen.



4.2.5 Print

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

4.2.6 Printing of screen section



This function gives you the possibility to print the ECG section, which can be seen on the screen.

4.2.7 Export



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

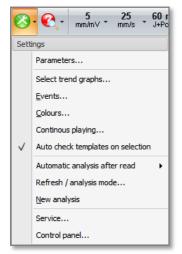
4.2.8 Export Current Samples



There is an opportunity to directly export the selected ECG section on the screen.

You can learn more about printing / exporting and its settings in <u>CHAPTER 7</u>.

4.2.9 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.

4.2.9.1 *Parameters...*

You can set parameters here like "Awake" and the "Special time", Rhythm analysis limits, options for V and SV events, ST, QT, SAECG and ECG-HR turbulence calculation options, filters for the ECG, paediatric options for easier QRS detection and filters for noise detection.

Since these parameters are very important and they need a detailed description, we will explain their uses and meanings in CHAPTER 5.

4.2.9.2 Select trend graphs...



By default, in the "Trends" window, you can see all these option at the first row in a list. In this menu, you can disable the ST diagrams, and enable these options instead.



4.2.9.3 Events...



You can set the order of the events or you can even enable or disable them from the list.

You can configure 3 different presets for the displaying and 1 for the printout.

After you configurated the presets, you can select from them on the toolbar.



4.2.9.4 *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.)

4.2.9.5 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.



4.2.9.6 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.

4.2.9.7 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.



4.2.9.8 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!

TIME:

4.2.9.9 *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).

4.2.9.10 *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 Parameters

5.1 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.

5.2 ECG-Rhythm:



On this tab, you can change the parameters of the rhythm analysis, the V, SV event definitions and there is an option to set the algorithm to only include N-N intervals in the maximum and minimum heart rate calculations.

5.2.1 Rhythm Analysis

5.2.1.1 Sinus Tachycardia from:

If the HR of an ECG section (on the AVG HR graph) is above this parameter and the QRS types in it are

dominant (N, R, L or B), the SW will mark it as Sinus Tachycardia.

5.2.1.2 Supraventricular Tachycardia from and -increase

These parameters are used for detecting Paroxysmal Supraventricular Tachycardia. The Paroxysmal Supraventricular Tachycardia is an ECG section, where the HR suddenly increases and then it returns back to normal after a short or a longer time (sustained or non-sustained). Depending on the settings (V, SV Event definitions), the algorithm will detect Supraventricular Tachycardia, if the HR of an ECG section (on the AVG HR graph) is above the "from" parameter and if the HR has increased compared to the previous section of the ECG more or equal to the "increase" parameter. The QRSs are not ventricular type. The "Supraventricular Tachycardia from" parameter is for setting the HR limit and the "Supraventricular Tachycardia increase" is for setting the rate of the increase. The last one is important to avoid detecting Paroxysmal Supraventricular Tachycardia instead of Sinus Tachycardia.

5.2.1.3 Ventricular Tachycardia from

Depending on the settings (V, SV Event definitions), the algorithm will detect Ventricular Tachycardia if the HR of an ECG section (on the AVG HR graph) with V type beats is above the "from" parameter.

5.2.1.4 Bradycardia below

The algorithm will detect Bradycardia where the HR of an ECG section (on the AVG HR graph) is below this parameter. This parameter affects Sinus-, Supraventricular- and Ventricular Bradycardia as well.

5.2.1.5 SVPR limit

This parameter is used for detecting single Supraventricular (SupraVentricular Premature Beat) type of QRSs. The single S type QRS is an early QRS which occurs earlier compared to the previous average RR intervals, calculated from dominant beats.

The value of the SVPB limit means the deviation from the regular RR intervals. The higher this value, the less single S QRS will occur.

5.2.1.6 *RonT below*

If a ventricular (V) QRS is closer to a previous dominant (N, R, L, B) QRS than this parameter (ms), it will be marked as an RonT event.

5.2.1.7 *Pause from*

If the RR interval between 2 QRS is higher than this parameter, it will be marked as Pause.

5.2.1.8 Shortest Atrial Fibrillation

This parameter is used for detecting Atrial Fibrillation. It forces the algorithm to delete AF events where its length is shorter than this parameter.

5.2.2 V, SV Event definitions

There are 4 possible options to show V and SV events:

- 1. CPL(2), RUN(3), TCH(>=4)
- 2. CPL(2), RUN(3), TCH_S(>=4), TCH_S(>=4)
- 3. CPL(2), TCH(>=3)
- 4. CPL(2), TCH S(>=3), TCH NS(>=3)

TCH_S = Sustained Tachycardia (>=30s)

TCH_NS = Non-sustained Tachycardia (<30s)

These options affect some summary table, so they will be showed according to this option. The "Ectopic Trends" menu is also affected.

It is important to know that the algorithm marks the ECG section as RHYTHM instead of TCH, if the HR of the ECG section (on the AVG HR graph) is below the "... Tachycardia from" parameter and it is more or equal to the "Bradycardia below" parameter. It will be marked as BRAD if the HR of the ECG section (on the AVG HR graph) is lower than the "Bradycardia below" parameter.

5.2.3 Only include N-N intervals in minimum and maximum heart rate calculation

The algorithm will calculate the minimum and maximum heart rate only from the dominant type of QRS (N, R, L or B), if this option is enabled.

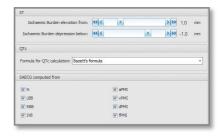
In case we run a new analysis of the record, default settings will be restored, so all previous editing will be lost.

5.3 ST/QT

5.3.1 ST

5.3.1.1 Ischaemic Burden elevation from

ST elevation, if the ST level on the ST graph is higher than this parameter. It is calculated per channels separately.



5.3.1.2 Ischaemic Burden depression below

ST depression, if the ST level on the ST graph is lower than this parameter. It is calculated per channels separately.

5.3.2 OTC

5.3.2.1 Formula for QTc calculation

These options are corrected QT calculation methods. The correction is based on the data of the QT curve (calculated from the SAECG) and the AVG HR graph.

5.3.3 SAECG computed from

The SAECG (Signal Averaged ECG) is calculated from intervals of QRSs per 10 seconds. You are able to choose which QRS types you want to use for the calculation of the SAECG.

5.4 ECG-HR Turbulence



5.4.1 HR range used for computation

The HRT calculation is only happens in case of a V beat, where the HR is within the range of the "HR range used for computation" parameter.

5.4.2 Risk factor

5.4.2.1 Slope below

The SW shows a risk factor, if the HRT Slope is lower than this parameter.

5.4.2.2 *Onset from*

The SW shows a risk factor, if the HRT Onset is lower than this parameter.

You can see these risk factors under the HRV / HR Turbulence menu.

5.5 ECG – Misc



5.5.1 ECG Filters

You can turn off and on the filters for the ECG.

IT IS HIGHLY RECOMMENDED TO LEAVE THEM TURNED ON (by default), because it may (quite likely) lower the quality of the ECG and the rhythm analysis will not be completely precise.

5.5.1.1 Smoothing



There are two types of smoothing. The first one is the Type I, which is a Slew Rate type filter. It allows the filtering on ECG sections, where the slew rate is low (no QRS). It might happen that in case of certain QRS shapes, the filter affects those as well.

The second one is filtering the baseline between the QRSs, which can be set in three options by intensity (Strong, Normal, Weak). This type of filter does not affect the QRSs, thus leaving them in their original shape. **Type II – Strong is the default.**

5.5.1.2 *Baseline*

It is a baseline-fluctuating filter.

5.5.1.3 *Mains* (50, 60Hz)

It is a circuit-interference filter.

5.5.2 Pediatric mode

5.5.2.1 QRS detection optimized for small children

In case of babies and small children it is common that the QRSs are very narrow. If this option is enabled, it allows the algorithm to detect very narrow QRSs as well.

5.5.2.2 Disable high amplitude signal exclusion

It is turning off modules in the noise-filtering system, which is used for detecting and marking narrow, high-amplitude and pulse-like QRSs as noise. In case of babies, the amplitude of the QRS can be up to 10-12mV high.

5.5.3 Invert channels

You can choose channels to show inverted (1-2-3CH). It is not allowed in case of records that was made by an EC-12H device. After modifying, a new analysis will be performed.

5.5.4 Disable channels

You can exclude channels from all of the analysis. After modifying, a new analysis will be performed. In case of the EC-12H devices, you are not able to disable the "I", "aVR", "aVL" and the "aVF" channels.

5.5.5 Pacemaker

Regardless of the set pacemaker type at the patient data, you can independently set it for the records here as well. It is useful when there are previous records in the database for the patient where he/she did not have pacemaker yet.

5.6 Noise detection



The Cardiospy software has fairly complex noise-filtering modules. These modules can be turned on and off. Besides, you can set the sensitivity of the noise-filtering if necessary.

5.7 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.



5.7.1 Statistical Limit

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).

5.7.2 Valid measurement ranges

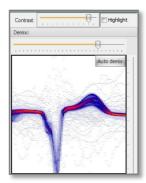
The program's analysis accepts BP values within these ranges. If the results of certain measurements are outside of this range the software takes the measurements out of the evaluation and marks them as invalid.

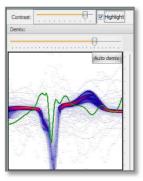
6 Editing and measuring options

6.1 Templates – functions

6.1.1 Using the Highlight function

If this function is on, QRS complex displayed in the ECG window will be marked by a continuous line in the Demix window.





The function is off

The function is on

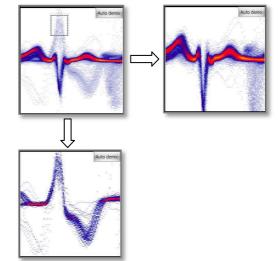
6.1.2 Manual demix

The purpose of this function is to clear the cluster of the inappropriate QRS complexes and artefacts. This function enables us to select one or more QRS complexes in order for them to be moved to a new cluster.

Select cluster (it is going to be a parent cluster)

Mark a rectangle in Demix window in any channel by pressing left mouse button.

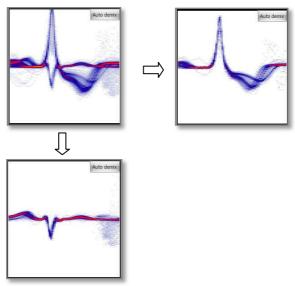
All QRS complexes can be moved to a new cluster (it is going to be a child cluster), which has at least one point within the rectangle.



The program automatically modifies and creates the QRS image characteristic of the given cluster. The created child cluster is marked in red. The marking remains on the parent cluster until a new cluster is marked.

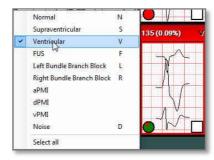
6.1.3 Auto demix

In the Auto Demix function we can "clean" the marked clusters of each channel. If a new cluster is created, the focus moves to the new cluster. The original cluster is marked with a red frame.



6.1.4 Editing the clusters

The type of a cluster can be changed by right-clicking the template. The chosen type will automatically appear next to each heartbeat of a cluster.



6.1.5 Merging of clusters

All the similar cluster types can be merged manually or by the drag-and-drop method familiar from Windows. This means that with the left mouse button we mark the cluster and while holding this button just move the marked cluster to the one with which we wish to merge, then release the button. The program allows merging only similar type of clusters, e.g. N can be merged with N, V with V etc.

Before completing the contraction, it is advisable to display only one particular type of group in the "Filter templates by" drop-down menu.

6.1.6 Cluster group operations

We can select all the clusters for group operations by holding the right mouse button, then choosing Select all.

We can select the specified multiple clusters for group operations by pressing and holding the Shift button while clicking the left mouse button at one point and pulling the cursor the desired clusters.

The selected clusters can be merged or their types can be modified together.

6.1.7 The function of the "Fix" button

By clicking on the "Fix" button, a certain type of QRS can be fixed in the marked cluster. Marking a new cluster invalidates all the previously set cluster types.



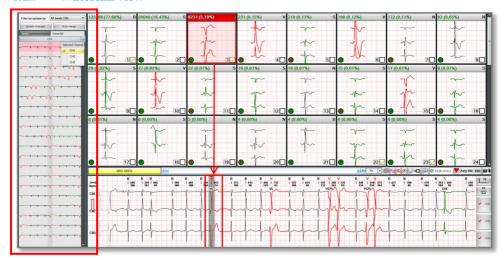
It is advisable to use this button, if we would like to modify the type of a complex cluster, with the exception of some QRS complexes.

If you click on the arrow next to the "Fix" button, then you can make all the elements of the selected template to fixed or unfixed.

6.1.8 Determination of QRS clusters

If you select a beat in the "Main" or "ECG" window and then go into the "Templates", then the focus will go to the cluster in which there is the appropriate QRS.

6.1.9 Waterfall view

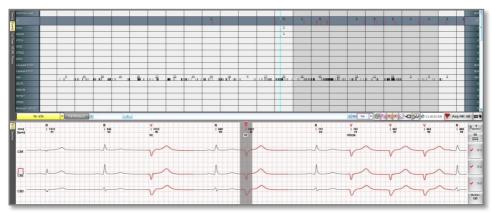


Next to the Demix option you can choose also the Waterfall method to expand a template. All the actions (renaming, deleting, QRS etc.) can be performed using this design. This way, you can quickly overview a lot of beats under each other from the same template at once, together with the surrounding beats.

6.2 Handling events

6.2.1 Sections where you can track and edit events

1. The easiest way to edit events is to go into the "Main / Events" menu.

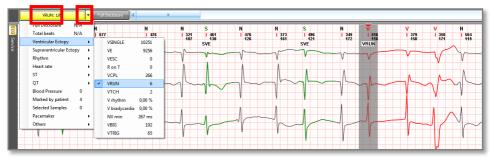


If you want to edit the elements of the list, please go back to CHAPTER 4.2.9.3.

In this list, you can find all the type of events separately. If you select a "single" (e.g. VE, SVE, RonT, etc.) or a "group" (e.g. CPL, RUN, TCH, etc.) type of event, then you can run through all of its elements and change them as you wish.

If you click on an event, then the "filter menu" will also change.

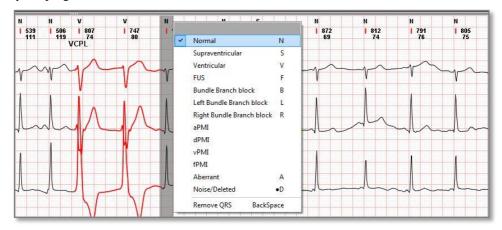
2. Using the "filter menu". You can find this menu on these tabs: Main, ECG (large window), Templates, Event summary.



In this menu, all type of events are listed. If you select an event, then in the ECG viewer (at the bottom of the screen), you can move through only between the fitting beats or beat groups, but you can edit every other beats as well.

6.2.2 Modification of unique QRS types

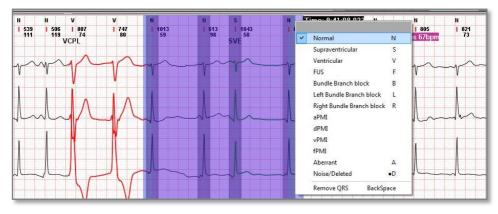
Right-click the relevant QRS and choose the appropriate QRS type from the list offered by the program.



6.2.3 Modification of group QRS types

Moving the mouse by holding the left mouse button mark all those QRS, which are found next to each other and the type of which you would like to modify.

If you have selected a group of beats, you can change their type by right click on one of its elements and select a type from the list.



You can also change the type of the beats using the proper keys of the keyboard. You can see the letters in the dropdown list.

6.2.4 Using the ECG ruler - measurement



We can measure time and amplitude by holding the left mouse button while moving the cursor, this way you select a certain section of the ECG curve.

Time: Represents the "current" time at the selection.

Selected interval: Represents the time interval of the selection.

Selected RR interval: Here we can see the number of the selected beats, the time interval between the first and last QRS and the average HR measured from the selection. Amplitude is measured by calculating the difference of the two points where the first and second ruler intersects the ECG curve.

6.2.5 Insert a QRS

Move the cursor to the point at which you intend to insert the selected QRS. While holding the left mouse button, click with the right mouse button. Choose the appropriate QRS type from the list offered by the program.

6.2.6 Remove a QRS

Choose the relevant QRS by the right mouse button and then choose "Remove QRS" from the list offered by the program.

As a result of QRS removal, the relevant QRS disappears from the QRS list, while it remains when marked as noise. We should remove QRS, if there is an artefact between the two QRS complexes of a real pause, which hinders pause detection. When the artefact has been removed, the pause becomes detectable. If several artefacts follow each other, it is advisable to rename them as noise, because their removal can create a pause.

6.2.7 Delete a single event

In the selected event type, we can delete the currently displayed event by pressing the button. When the event has been deleted, all the QRS complexes belonging to this event type will automatically be renamed as noise.

6.2.8 Delete a group of events

In the selected event type, we can delete all events by pressing the button. When the event has been deleted, all the QRS complexes belonging to the pertinent event will automatically be renamed as noise.

6.2.9 Using the Fix button

The "Fix" button is a great help when you want to delete a group of events, but you want to exclude some from the deleting or when you want to delete only the "fixed" beats from this type of event.



With this button, you can delete all the "unfixed" events from the selected type of event, while the "fixed" events will remain.



With this button, you can delete all the "fixed" events from the selected type of even, while the "unfixed" events will remain.



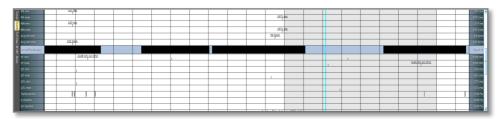
With this button, you can delete a single beat or you can delete all beats within a selection from the same type of event.

These delete functions are not allowed in case of interval type events (e.g. Atrial fibrillation, Atrial flutter, AV I, AV II, etc.).

6.2.10 Interval type events

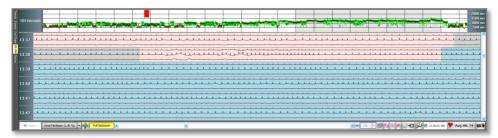
You can edit these interval type events by three possible ways:

6.2.10.1 *Main / Events*



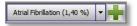
If you hold the "Shift" button on your keyboard and the left mouse button on the mouse while dragging it on the screen, then (for example) the software will ask you if the selected range is an Atrial Fibrillation or not. You can also delete falsely detected intervals this way by clicking on the "No" button.

6.2.10.2 *Main / AF/AV*



Here, it is enough to hold the left mouse button and drag the mouse on the full view.

6.2.10.3 In the "ECG viewer"



The other way here is to click on the "+" button next to the name of the selected event type.

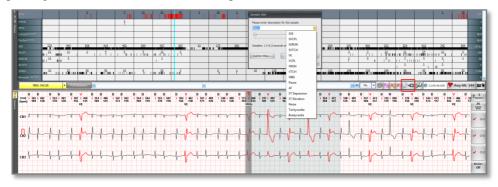
A new window will pop up, where you can select an interval and tell it to set this interval to this type of event or delete from it.

You can type the start and the end of the interval manually or you can choose the slide to select the range of the interval.



6.2.11 Selecting actual samples for printing

You can select intervals in the program with the help of this button and these samples will appear on the printed report as well. The samples can be named and own default titles can be prepared which can be set easily. The length of the sample selected for printing can also be modified with the help of the slider.



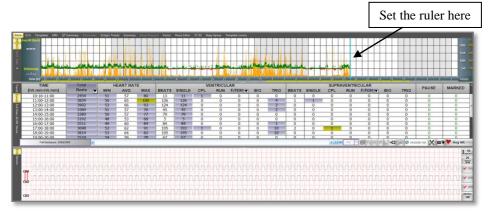
6.2.12 Erasing the end of the record

If the end of the record is lead-off and does not contain any ECG signals it is possible to erase the unnecessary part from the end of the record.

NOTE: Once you have erased the end of the record it can not be recovered anymore.

The process of the erasing:

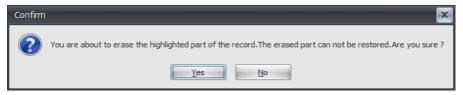
1. Setting the ruler: mark the starting time of the section you want to delete.



2. Click on the scissor icon.



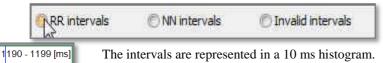
3. A warning window will pop up. If you click on No button, nothing happens. After clicking the Yes button the section after the selected point (marked with grey bar) will be erased definitively.



6.3 HRV – Editing and validation

In the HRV window we can validate or invalidate RR or NN intervals individually or as a group.

Choose the Intervals graph to edit intervals. The displayed intervals can be RR, NN, or invalid intervals.

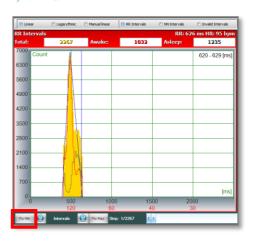


6.3.1 Fixation of RRmin, RRmax, NNmin, NNmax

These parameters will appear in the reports and in other calculations as well, so it is important to have their precise values.

The HRV window enables a fast editing of these values.

To edit the RRmin, choose "RR intervals". With the left mouse button move the cursor above the ruler in the graph of HRV intervals and then move it horizontally to the point where you want to set the RRmin. On that point, you can see how many intervals are in the selected range. From now, you can move between the RR intervals more precisely in a 0-10 ms



interval. You can do it with the slidebar at the middle, with the arrow $(\leftarrow \rightarrow)$ buttons on the keyboard or with these buttons:



If you have selected the RR interval that you wish to set as RRmin, click on the "Fix Min" button.

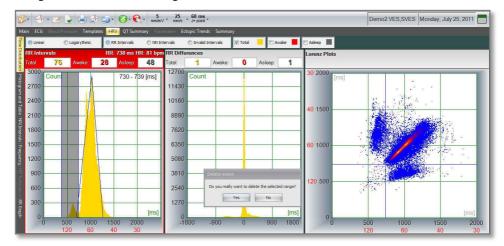
The same procedure must be followed for editing the RRmax, NNmin, and NNmax.

6.3.2 Invalidation of single intervals

The currently displayed interval can be invalidated by clicking on the button next to the slidebar at the middle. Invalidation means that intervals of the given types are ignored by all algorithms during the evaluation. The QRS complexes belonging to the given interval retain their original type.

6.3.3 Invalidation of groups of intervals

By holding the 'Shift' button you can select a wider interval if you drag the mouse through a section while holding the left mouse button as well.



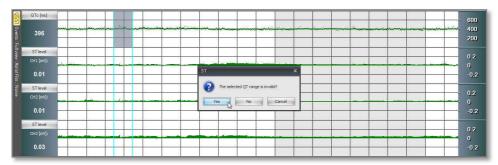
6.3.4 Recovery of invalid intervals

The invalid intervals can be displayed by selecting 'Invalid intervals'. There are opportunities to validate individually by pressing the button or collectively by holding Shift + left mouse. This way we can restore more units at the same time.

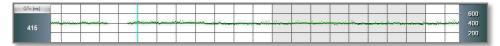
6.4 ST, QT, QTc graph

6.4.1 Invalidate selected interval

We can select an interval in the QT, QTc and AT graphs by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, these intervals can be invalidated. This action has no effect on intervals which have already been invalidated.



Result of the invalidation:



6.4.2 Restoring invalidated intervals

We can select an interval in the QT, QTc and AT graphs by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, these invalidated intervals can be restored. This action has no effect on valid intervals.

6.4.3 Deleting Min, Max values

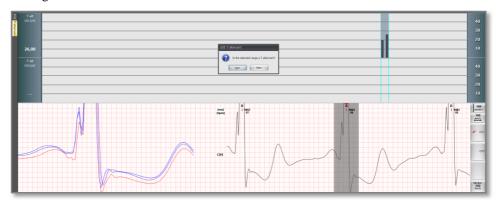
We can select the desired parameter in the Event menu point and then click on the button in case the selected value is not acceptable. Deleting can be repeated until the result is acceptable.

6.5 T-alternant

6.5.1 Delete the T-alternant sections

There are multiple options to delete T-alternant sections.

One option is to delete by using the Mand the buttons. Clicking on the deletes the T-alternant section on which the ruler is placed at the moment, while clicking on the button deletes all T-alternant sections.



Another option is to select a desired interval by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, the software prompts us to answer a question concerning what to do with the selected section next. In case we decide to mark the selected section not as T-alternant section, all the corresponding T-alternant sections will be deleted. On the manually deleted T-alternant sections the automata analyses does not show more T-alternant, but manually the T-alternant may be marked to any place.

6.5.2 Insert the T-alternant sections

Select a desired interval by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, the software prompts us to answer a question concerning what to do with the selected section next. If we choose this section, as T-alternant section, the T-alternant mark will appear on it. Manually marked T-alternant section may be deleted according to ones demand.

6.6 Noise editing

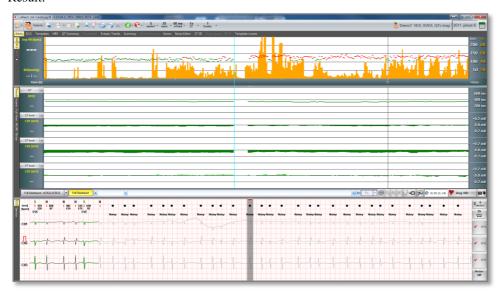
6.6.1 Editing in the Main / Noise window

6.6.1.1 Invalidate selected interval

We can select an interval by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, the software prompts us to answer a question concerning what to do with the selected section next. In case we decide to mark the selected section as noise the software marks all pertaining QRS complexes as noise, which means they will be excluded from further analysis.



Result:

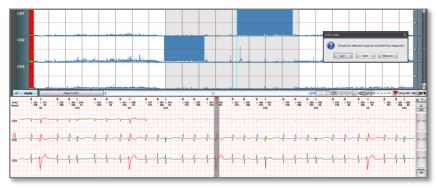


6.6.1.2 Restoring invalidated intervals

We can select an interval by pressing and holding the Shift button while clicking the left mouse button at one point of the ECG curve and dragging the cursor to the desired point. When the selection has been made, the software prompts us to answer a question concerning what to do with the selected section next. In case we decide to mark the selected section as not noise the software restores all pertaining QRS complexes, which means that they will be included in further analysis.

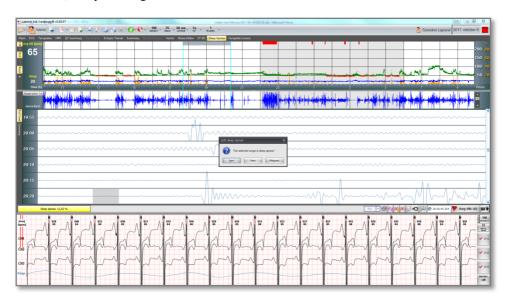
6.6.2 Editing in the Noise Editor

You can select intervals as noise **per channels separately**. If you hold the "Shift" button on your keyboard and the left mouse button on the mouse while dragging it on the screen, then the selected range can be excluded from the diagnosis.



6.7 Editing in Sleep Apnea

You can edit Sleep Apnea the same way as e.g. Atrial Fibrillation. You can delete events one by one, by selecting a period (by holding "Shift" button and dragging the cursor on the HR graph while holding the "left click" of the mouse or in the Full view of Sleep Apnea by dragging the cursor on the Full view while holding the "left click" of the mouse) or by deleting all of them.



Events will be deleted if you click on the "No" button, but you can also insert Sleep Apnea event by clicking on the "Yes" button.

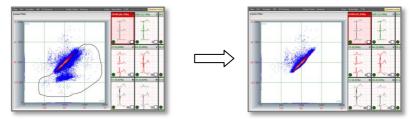
You can read more about how to edit events in CHAPTER 6.2.

6.8 Editing in Template-Lorenz

In this menu, you can designate any area on the graphic interface to demix the selected template manually. You can do it by moving the cursor on the graph from where you want to start to draw, then hold the left mouse button and drag it in any shape until you get back to the starting point.

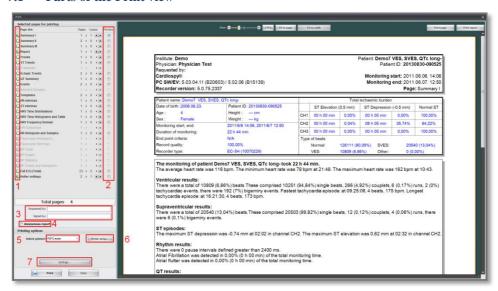
If you want to verify your selection and delete it from the selected template, then double-click on the point where you have started / ended the drawing.

If you want to cancel the drawing, just move the cursor out of the graph.



7 Print and Export

7.1 Parts of the Print view



You can select the pages for printing by tick or untick the checkboxes next to the name of the pages.

You are able switch between the pages that you want to see with the radio buttons next to the name of the pages.

It is possible to type in the name of the doctor who is requested the examination and who signed the report.

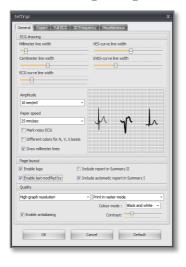
With this checkbox you can hide the personal data of the examined patient, making the report anonymous.

Here you can select the printer (or file format in case of exporting) you want to use from the list. First you have to set the printer in Windows to be able to choose it from here.

General printer settings. Number of copies, orientation, etc.

Print view settings. More in the next sub-chapter.

7.2 Printing settings



7.2.1 General:

ECG drawing:

- 1. Here we can set the thickness of the graph paper, the ECG curve, the VES and the SVES curve on the pages.
- 2. In the whole ECG view the program completely cuts the noisy sections, so they will not appear on the reports.
 - 3. You can print beats with different colours.
- 4. You can set the visibility of the millimetre lines on the reports.

Page layout:

- 1. You can show/hide the logo at the header of the report.
- 2. It is possible to make the name of the expert and the date of the last modification visible on the "Report" page (if you have).
- 3. You are able to show/hide the automatic report on the Summary I page.
- 4. You can enable to show the interpretation ("Report") on the Summary II page.
- 5. Quality:
- 6. You can set the quality of the printing to low or high graph resolution.

7. You are able to 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."

8. In "Black and white" colour mode, it is possible to set the contrast of the millimetre paper lines.

7.2.2 Export

On this page, you can set the file names of the exported reports and the resolution of the exported images.

7.2.3 Full ECG

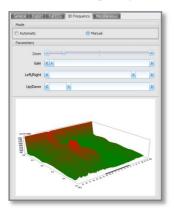
Display settings:



- 1. You can set the visible interval of ECG on the Full ECG (Total) page to "Hour" and "Half hour".
- 2. You are able to select the channel that you want to see on the Full ECG (Total) page.
- 3. It is possible to change the amplitude of the ECG on the Full ECG (Total) page.
 - 4. Duration:

You can select the interval of the ECG that you want to print on the on the Full ECG (Total) page.

7.2.4 3D Frequency



Mode: You can set it to automatic or manual.

If you select manual:

Parameters:

- 1. You can zoom-in and out for better view.
- 2. You can increase the gain to set the range of the [ms²/Hz*1000] parameter.
- 3. You can rotate the diagram to left and right.
- 4. You can rotate the diagram to up and down.

7.2.5 Miscellaneous

You can show / hide a table with the marked samples at the bottom of the "Selected samples" page.

7.3 Exporting



The only thing that is different in this view is the "Printing options" section.

Instead of a printer, you can choose from different file formats (PDF, Jpeg, BMP, Png, Dicom, Jpeg CSV and DCM/PDF file).

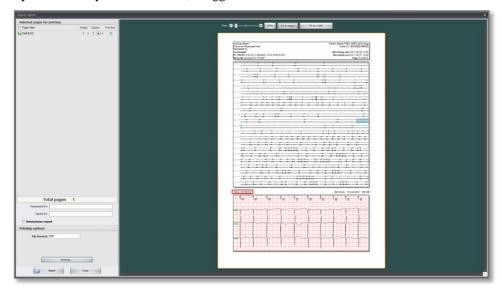
You are able to export the reports by "One file / page" and "One file / page".

7.4 Print / Export current samples

It is possible to print / export the currently selected ECG section (in the main window).



If you select only 1 or 2 channels, a bigger interval of ECG will be seen.



8 Calculation and Evaluation methods

8.1 ECG

8.1.1 HR calculations

Heart rate (HR graph, Avg HR min, Avg HR max, ECG widow)

$$Avg\ HR = \frac{1000*60}{\sum_{10s} RRi}$$

AvgHR is computed from RR intervals in every 10s interval.

$$Act HR = \frac{1000 * 60}{\sum_{window} RRi}$$

ActHR is computed from the ECG stream on display.

8.1.2 QT, QTc and ST calculations

Corrected QT (Bazett's formula): $QT_c = \frac{QT}{\sqrt{RR}}$

ST level:

$$\mathbf{ST} = \mathrm{ECG}[\mathrm{J}+] - \mathrm{ECG}[\mathrm{Izo}]$$

8.1.3 Turbulence and RR interval calculation:

Determining valid VES beats:

There are at least 3 sinus beats before the VES

There are at least 20 sinus beats after the VES

$$RR_0 \le 0.8 * RR_{-1}$$

$$RR_1 >= 1.2 * RR_{-1},$$

The heart rate in the pertinent section falls into the HR range which can be set in the Settings menu

Calculation of Reference RR: RR_{ref} =
$$\frac{\sum_{i=15}^{20} RR_i}{5}$$

VES is omitted when any RR interval (except RR₀ and RR₁) is

< 300 ms,

2000ms.

 $RR_{i-1} > 300ms$,

 $RR_{i} / RR_{ref} > 1.2 \text{ or } RR_{i} / RR_{ref} < 0.8$

Averaging RR intervals: Average RR intervals are computed from RR intervals before and after the valid VES beats in every hour.

Calculating Turbulence slope: The maximal positive slope of an average of 5 sinus beats occurring after RR1 (compensatory pause) applied to one beat.

8.1.4 Calculation criteria for VES and SVES events:

VSINGLE – Ventricular single beat:

It contains three types of events in Cardiospy:

- 1. VE Ventricular Beat (V): Ventricular extrasystole
- 2. **VESC:** Escape type ventricular beat
- 3. **RonT:** If a ventricular (V) QRS is closer to a previous dominant (N, R, L, B) QRS than the "RonT below" parameter (ms) in the Settings / Parameters / ECG-Rhythm menu, it will be marked as an RonT event.

VCPL - Ventricular Couplet:

Two successive ventricular beats.

VRUN - Ventricular Run:

Three successive ventricular beats.

VTCH - Ventricular Tachycardia:

Depending on the settings (V, SV Event definitions), the algorithm will detect Ventricular Tachycardia if the HR of an ECG section (on the AVG HR graph) with V type beats is above the "Ventricular Tachycardia from" parameter.

VTCH_S – Ventricular Sustained Tachycardia:

Sustained Ventricular Tachycardia (>=30s)

VTCH_NS - Ventricular Non-sustained Tachycardia:

Non-sustained Ventricular Tachycardia (<30s)

VRHYTHM – Ventricular Rhythm:

Depending on the settings (V, SV Event definitions), the algorithm will detect Ventricular Rhythm, if the HR of the ECG section (on the AVG HR graph) is below the "Ventricular Tachycardia from" parameter and it is more or equal to the "Bradycardia below" parameter in the Settings / Parameters / ECG-Rhythm menu.

VBRAD – Ventricular Bradycardia:

Depending on the settings (V, SV Event definitions), the algorithm will detect Ventricular Bradycardia, if the HR of the ECG section (on the AVG HR graph) is lower than the "Bradycardia below" parameter in the Settings / Parameters / ECG-Rhythm menu.

VBIG – Ventricular Bigeminy:

A series of subsequently alternating Ventricular and dominant beats.

(Ventricular-dominant-Ventricular-dominant)

VTRIG – Ventricular Trigeminy:

A series of subsequently alternating Ventricular and dominant beats.

(Ventricular-dominant-dominant-Ventricular-dominant-dominant)

SSINGLE – Supraventricular single beat:

It contains one type of event in Cardiospy:

1. SVE – Supraventricular beat (S): Supraventricular extrasystole

SVCPL – Supraventricular Couplet:

Two successive Supraventricular beats.

SVRUN – Supraventricular Run:

Three successive Supraventricular beats.

SVTCH - Supraventricular Tachycardia:

Depending on the settings (V, SV Event definitions), the algorithm will detect Supraventricular Tachycardia, if the HR of an ECG section (on the AVG HR graph) is above the "Supraventricular Tachycardia from" parameter and if the HR has increased compared to the previous section of the ECG more or equal to the "Supraventricular Tachycardia increase" parameter.

SVTCH_S – Ventricular Sustained Tachycardia:

Sustained Supraventricular Tachycardia (>=30s)

$SVTCH_NS-Ventricular\ Non-sustained\ Tachycardia:$

Non-sustained Supraventricular Tachycardia (<30s)

SVRHYTHM – Ventricular Rhythm:

Depending on the settings (V, SV Event definitions), the algorithm will detect Supraventricular Rhythm, if the HR of the ECG section (on the AVG HR graph) is

below the "Supraventricular Tachycardia from" parameter and it is more or equal to the "Bradycardia below" parameter in the Settings / Parameters / ECG-Rhythm menu.

SVBRAD – Supraventricular Bradycardia:

Depending on the settings (V, SV Event definitions), the algorithm will detect Supraventricular Bradycardia, if the HR of the ECG section (on the AVG HR graph) is lower than the "Bradycardia below" parameter in the Settings / Parameters / ECG-Rhythm menu.

SVBIG – Supraventricular Bigeminy:

A series of subsequently alternating Supraventricular and dominant beats.

(Supraventricular-dominant-Supraventricular-dominant)

SVTRIG – Supraventricular Trigeminy:

A series of subsequently alternating Supraventricular and dominant beats.

(Supraventricular-dominant-dominant- Supraventricular -dominant-dominant)

PAUSE:

The time between two heartbeats reaches or exceeds the "Pause from" parameter in the Settings / Parameters / ECG-Rhythm menu.

8.1.5 Interpretation of HRV time domain parameters

(Reference: Circulation 1996, 93:1043-1065, 1996 American Heart Association Inc.)

NN interval:

The interval between two consecutive normal beats. The dominant QRS complexes are interpreted as Normal-N beats.

NN min:

The shortest NN interval measured in the record.

NN max:

The longest NN interval measured in the record.

NN avg:

The sum of NN intervals divided by the number of normal beats.

N-Normal beats:

The number of normal beats during in the record.

SDNN:

The standard deviation of NN intervals in relation to the total recording time. The individual NN intervals must be counted during measurement time. The NN distribution function is obtained by representing these values, by calculating the standard deviation of which the SDNN values measured in ms are obtained. As the SDNN value greatly depends on measurement time, it is recommended to calculate it for 24 hours every time. In addition, it is the only way to interpret properly the comparison of the data with normal values represented in the reference, because these values refer to 24-hour recordings. (Normal range for 24 hours is: 102 - 180 ms)

SDANN:

Standard deviation of the averages of NN intervals in every 5-minute segment of the entire recording. The NN intervals are averaged for every five minutes, and the distribution function is obtained by representing the frequency of the averages. The SDANN parameter is obtained by calculating the standard deviation. (Normal range for 24 hours: 92 - 162 msec)

RMSSD:

The squares of the differences between consecutive NN intervals are added up, divided by the number of the intervals, and taken the square root of.

This value is the RMSSD calculated for the total measurement time. (Normal range for 24 hours: 15 - 39 msec)

SDNNi:

The standard distribution of NN represented is calculated for every five minutes; the values are added up and averaged for the total measurement time.

SDSD:

Standard distribution of differences between consecutive NN intervals.

The distribution of the difference between consecutive NN intervals is represented, the SDSD parameter is obtained by calculating the standard deviation, which is interpreted for the total measurement time.

pNN50:

The value of pNN50 parameter in percentage is obtained by counting the consecutive NN interval couplets having a difference greater than 50 msec, dividing it with the total count of NN intervals, and multiplying by 100.

HRVTi:

Approaching the RR distribution linearly represented with a triangle that covers the given distribution as fully as possible. The HRVTi parameter is obtained by calculating the differences between the intersections of the given triangle and the time axis.

8.1.6 Interpretation of HRV frequency range parameters

(Reference: Circulation 1996, 93:1043-1065, 1996 American Heart Association Inc.)

Total power [ms²]:

Efficiency spectrum 0.03125 – 0.40625 Hz

LF [ms²]:

Efficiency spectrum in the low frequency range 0.03125 – 0.15625 Hz

HF [ms²]:

Efficiency spectrum in the high frequency range 0.15625 – 0.40625 Hz

Normalized values:

$$LFn[\%] = \frac{100 * LF}{LF + HF}$$

$$HFn[\%] = \frac{100 * HF}{LF + HF}$$

The parameters are calculated according to the Wavelet Packets method.

8.1.7 Mathematical methods applied for calculating parameters

Standard deviation:

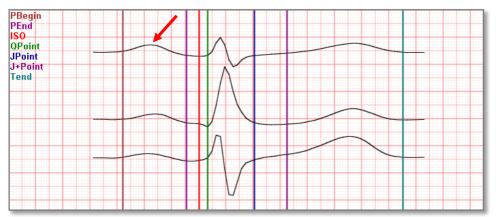
$$SD = \sqrt{\frac{\sum_{i=1}^{N} (Xi - M)^2}{N}}$$

Root Mean Square:

$$RMS = \sqrt{\frac{\sum_{i=1}^{N} (Xi)^2}{N}}$$

8.1.8 P-curve analysis

The Cardiospy is able to detect the P-curve:



8.2 BP

8.2.1 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:

$$24 * \frac{\sum_{(i=1)}^{N} (Data_i - Norm_i) * Time_i}{\sum_{(i=1)}^{N} Time_i}$$

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

8.2.2 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.

9 Troubleshooting and Maintenance

9.1 Firmware update

With every new Cardiospy version, we also **update the Firmware** (internal software of the device) **of V6 Holters** (serial number starts with 1602xxxx or higher). To be able to enjoy the advantages of it, an updating process is required. To update the Firmware of your device(s), please follow the following steps (takes approx. 0,5-1 min):

- 1. Connect the Holter device to the PC with the data transfer cable! Make sure that you do not have battery in the device!
- 2. Wait for the pop-up window of the automatic record reading! After the reading has been finished (close this window if the record has been read already), then a new firmware update window should appear.
- Click on the Update button!



4. Wait for the process to finish! If you break this process, you will have to start the update from the beginning!



5. Now disconnect the cable from the device! If you do not continue the process from this point, THE DEVICE WILL NOT TURN ON!!!



- 6. Now connect the cable back to the PC! If you left the battery in the device during the firmware deleting process, now please remove it before you connect the cable back. LEAVING THE BATTERY IN THE DEVICE WILL PREVENT THE PROCESS TO BE CONTINUED!
- 7. Click on the Update button once again! At this point the software will copy the new firmware to the device. DO NOT BREAK THIS PROCESS OR THE DEVICE WILL NOT TURN ON and the process must be repeated!!!
- 8. After the updating has been finished, you should be confirmed by this window:



9. The update was successful. Now click on the Close button. After this point, you can continue to work with your device and enjoy the improvements and new functions!

9.2 Troubleshooting

Error / Event	What to do?
BATTERY ERROR	Batteries are not properly charged in the recording unit. Please use well-charged batteries.
LEAD OFF ERROR	Please place the lead back properly.
COMMUNICATION ERROR	Please check if the connection between the recorder unit and computer is working properly.
NOISE ARTIFACTS ON ECG SIGNAL	Please check if all the electrodes are securely attached to the patient. The electrodes must be applied with sufficient care and expertise in order to make good quality recording.
SELECTED PAGE CAN NOT BE PRINTED	Check if the printer selected is turned on. If you have selected a local printer, check if it is connected to the computer.
RECORDER DOES NOT RECORD FOR 24 HOURS	Please make sure that you use well-charged batteries. Recharge the batteries only with the supplied battery charger according to the enclosed instructions. Please use batteries only of the same type and capacity.
Warning No patient cable connected!	Please connect the patient cable to the Recorder.
⊗ ■	Please Read the latest record.
Cannot start	Please connect the appropriate patient cable to the recorder unit.
- 7 . 235. 381.3.	Please check if the batteries are charged properly.

Error / Event	What to do?
Warning Not supported patient cable!	Please connect the appropriate patient cable to the recorder unit. The compatibility of cables depends on the type of recorder being used.
Information USB connection detected.	The recorder is connected to the USB port.
Information Recording started.	Recording has started successfully.
Information Recording stopped.	Recording has stopped.
€C-3H v5.0.76	It is the start-up screen of the recorder, indicating the recorder configuration type.
Ch1 ch2 ch3	ECG sign, which appears on the recorder's display during the monitoring process.
Starting	The recorder starts.

TROUBLESHOOTING

Error / Event	What to do?
Information	A message which appears in the upper part of LCD in case of informing.
Warning	A message which appears in the upper part of LCD in case of warning.

9.3 Sending a bug report

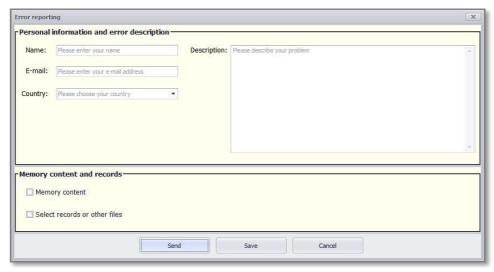
Creating Blackbox:

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 with the Print Screen button, then import it to Paint with CTRL+V and 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.

9.4 Maintenance and Calibration

9.4.1 Calibration

Calibration of the devices 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.

9.4.2 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.

Cleaning of 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.

10 Technical Specifications

10.1 Specification table of Holter recorders (EC-2H; EC-3H; EC-12H)

TECHNICAL SPECIFICATIONS OF DIFFERENT HOLTER SYSTEMS			
Type of Holter Recorders	EC-2H	ЕС-3Н	EC-12H
Bipolar ECG Channels	1, 2	1, 2, 3	1, 2, 3
Other ECG Channels	-	+PM, Nehb	+PM Standard 12 CH, Nehb
Respiration	-	Yes	Yes
Number of snap type Leads	3, 5	3, 4, 5, 7	3, 4, 5, 7, 10
The battery can be changed during recording	Yes		
Recording duration maximum (with battery changing)	336h		
Dynamic Bandwidth	±20 mV		
DC Offset Range	±600 mV		
Frequency Response maximum	0.05 Hz 150Hz		
Sampling Rate	125 Hz, 250 Hz, 500 Hz, 1000 Hz		
Recording Rate	125 Hz, 250 Hz, 500 Hz, 1000 Hz		
Common Mode Rejection Ratio	120dB		
A/D Resolution	16 bit		
Input impedance	>100 MΩ		
D C	1x1.2 V AAA NiMH		
Power Source		AAA alkaline)	
Battery Life	min. 24 h	, up to 48 h usi	ng a high-capacity battery

SPECIFICATION TABLE OF HOLTER RECORDERS (EC-3H/ABP) ECG HOLTER SYSTEM

TECHNICAL SPECIFICATIONS OF DIFFERENT HOLTER SYSTEMS	
Storage Card Capacity	built-in 2GB (microSD)
Internal Voltage (max)	3.3 V
Display	LCD (Grey Scale 160x100 pixels)
Movement detection-3D	Yes
Patient Event button	Yes
Monitoring ECG	On PC via Bluetooth and on LCD as well
Reading Record	via USB cable
International Protection Rating Against Water: IPX0	Yes
Size	53 x 67.5 x 18.5 mm
Weight	~ 50 g

10.2 Specification table of Holter recorders (EC-3H/ABP)

TECHNICAL SPECIFICATION I.	
Bipolar ECG Channels	1, 2, 3
Other ECG Channels	NEHB +PM
Number of snap type Leads	3, 4, 5, 7
Recording Period (hours)	24, 48, 72 h
The battery can be changed during recording	Yes
Dynamic Bandwidth (min)	±20 mV
DC Offset Range (min)	±800 mV
Frequency Response (max)	0.05 Hz 150Hz
Sampling Rate	256 Hz 2048 Hz
Recording Rate	128 Hz 1024 Hz

Common Mode Rejection Ratio (min)	120dB
A/D Resolution	16 bit
Input impedance (min)	100 MΩ
Power Source	2 x 1.2 V AA rechargeable batteries of minimum 2500 mAh capacity or 2 x 1.5V AA high quality alkaline batteries
Battery Life (min)	24 hours
Storage Card Capacity	2GB (μSD)
Internal Voltage (max)	3.3 V
Movement detection-3D	Yes
Monitoring ECG	On PC via Bluetooth
Reading Record	via USB 2.0 (USB A – HDMI)
International Protection Rating Against Water: IPX0	Yes
Size	Approx. 125 x 70 x 33 mm
Weight	Approx. 250 g (incl. Batteries)

SPECIFICATION TABLE OF HOLTER RECORDERS (EC-3H/ABP) ECG HOLTER SYSTEM

	TECHNICAL SPECIFICATION II.
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 Transducer Accuracy:	± 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.
Clinical	Meets accuracy requirements of ANSI/AAMI
Accuracy:	SP10:2002(R)2008, EN1060-4:2004 and ISO
	81060-2:2009.