

User Manual

CardioExplorer

Holter Analysis

Software



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CardioExplorer

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All information's included in this documentation an the corresponding software can be changed without any specific announcement for technical progress.

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1. Introduction

With the purchase of the new CardioScout of SR-Medizinelektronik you receive an innovative analysis software. Together with one of our small and easy to use Holter recorder you are the owner of a compact and trend setting unit.

General

The CardioScout is certified by CE and meets the requirements of the 93/42/EWG. It is designed to meet the standards EN 60601-1, 60601-1-1 (IEC 601/VDE 750) and IEC 1157 and complies with the guidelines issued by German Association of Medical Insurance Companies. Before using accessories produced by another manufacturer make sure that all safety standards are proved by a authorized examining board. (conformity certification). All accessories connected to the units of CardioScout shall comply with appropriate IEC/UL/CAN standards.

Additional equipment used with analog and digital interfaces of the system need to veritably meet the requirements for the according EN specifications, (e.g. EN 60950 about Safety of information technology equipment and EN 60601 Medical electrical equipment). All configurations must suffice the current release of the systemnorm EN 60601-1-1. The user of additional equipment in input and output interfaces is configurating the system and becomes responsible for the compliance with regulations of the current version of the the systemnorm EN 60601-1-1. For further inquiry contact your local specialist dealer or your technical support.

Included in Delivery

This package includes the following components:

- 1 1 x CardioExplorer Software (CD or USB-Stick or Download)
- 2 1 x This manual (printed or in PDF version)

2. Putting into Operation

Connection, assembly and installation of CardioExplorer Holter-ECG System

CardioExplorer Software Installation

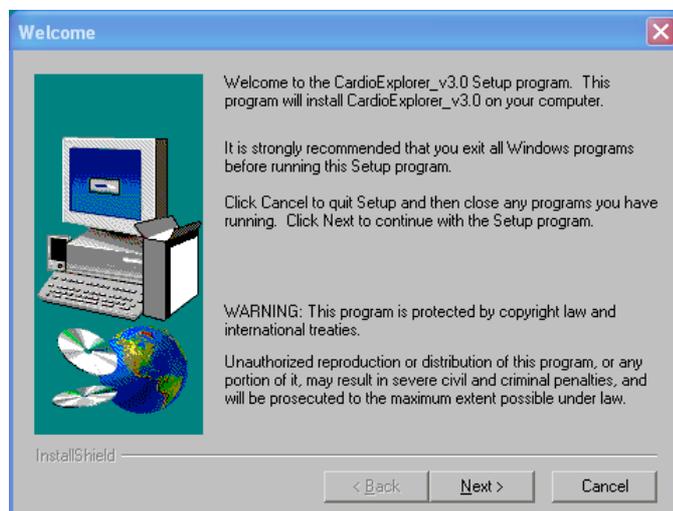
To install the software follow this procedure:

Insert the USB memory stick into the USB connector of your computer.

If installation is not starting automatically, please Start the Setup File manually.

The following menu will appear:

Press „Next“, to start installation



After software is installed successfully, press „Finish“ to complete setup



CardioExplorer Registration

During installation the system has placed a new Scout Icon on your desktop. Please double click it to start the CardioExplorer software.



scout

Starting first time, you will see the CardioExplorer Registration sheet:

Please fill in your personal information and choose the program features you like to install.

The serial number is detected automatically. Edit or change is not possible.

After typing in all information, press "Print" to print out your registration information.

Alternatively you can generate a screenshot of the registration menu by pressing „Alt" + "PrScr". This will copy a graphic of the registration menu into the clipboard, and after that you can paste it into a document or E-Mail.

Please fax or E-Mail your registration information to SR-Medizinelektronik, fax number +49 711 9144651, E-Mail: Info@sr-med.de, and you will receive your registration key.

After receiving the key, type it into the registration sheet and press „Register“ to decontrol the software.

Through this action we follow our manufacturer obligation to take care about all installed systems. In addition we use this information for warrenty purposes

Login

The CardioExplorer software is developed for a user profile use. This profiles can be loaded during our login procedure. The configuration of different users is definable in the Preferences (Pferencies -> User Configuration).

For your first Login please choose the default user SYSADMIN and use also **SYSADMIN** for password.



Login

Login name: SYSADMIN

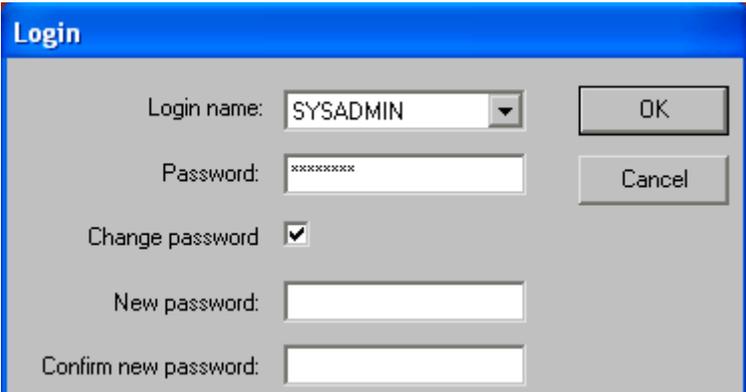
Password:

Change password

OK Cancel

There is the possibilty to change the password directly. Please activate the “change password” icon and choose your new password.

Press OK.



Login

Login name: SYSADMIN

Password: *****

Change password

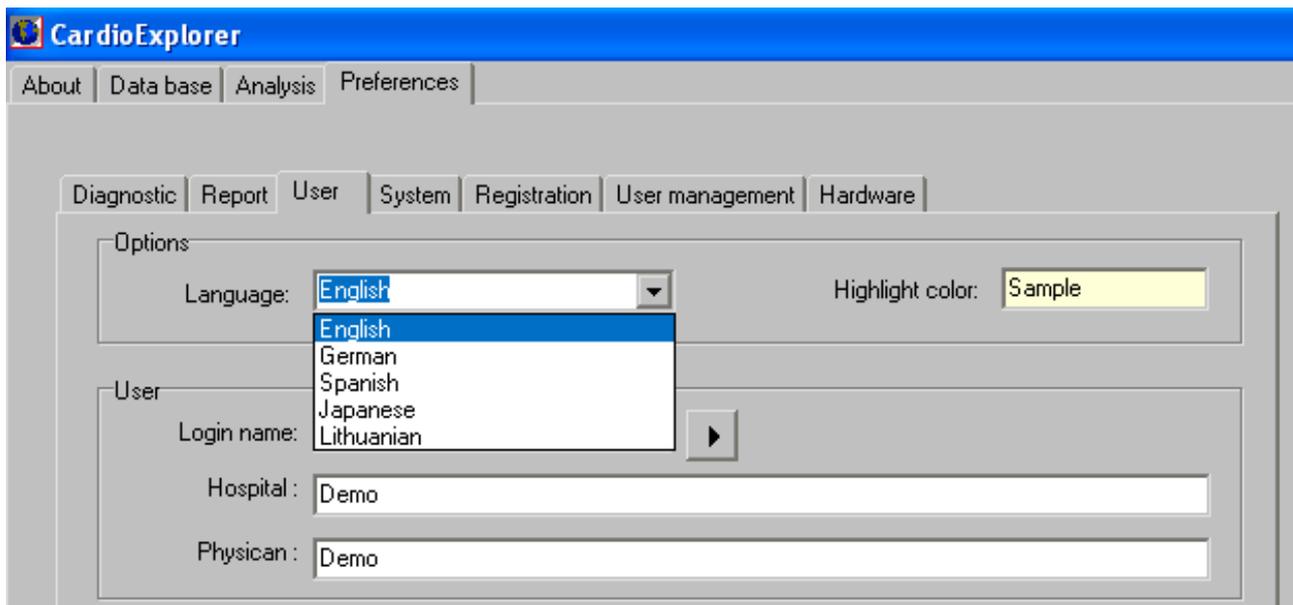
New password:

Confirm new password:

OK Cancel

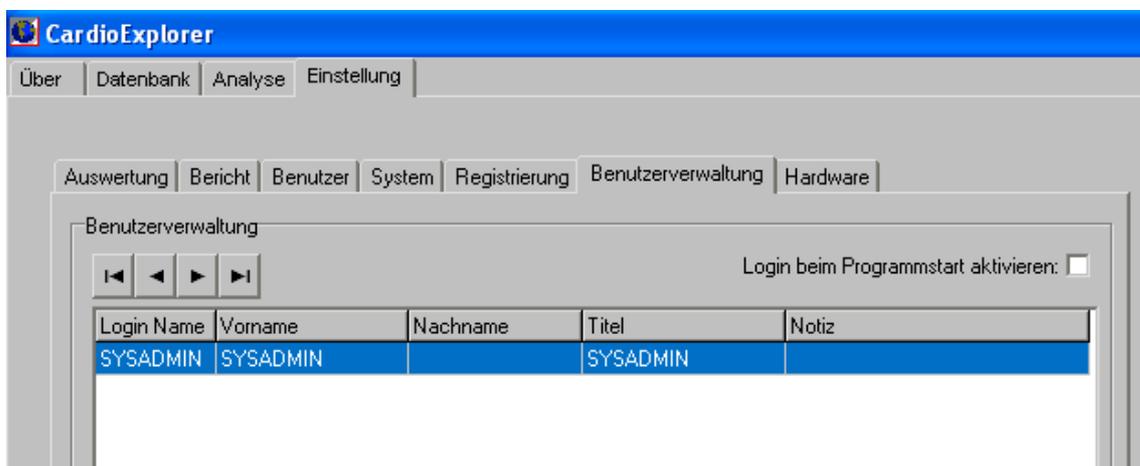
Choose your language

The default language of CardioExplorer is English. If you like to have another language please go to Preferences -> User and choose your language. If you have done this the software will restart automatically with the new language.



Activate / Deactivate the Login procedure

If you don't like to have the login procedure, you can disable it. After login into CardioExplorer software please choose the sheet **Preferences -> User Management** and deactivate the option **Login procedure at startup**



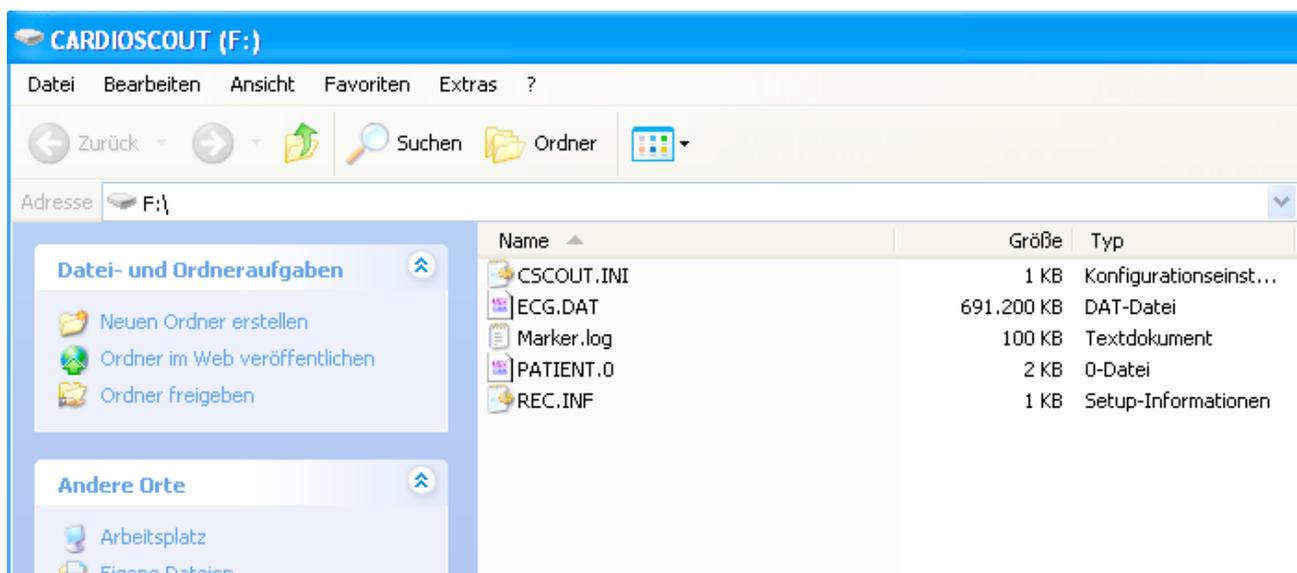
USB installation of the ECG recorder

Connect your ECG recorder with the USB data/charger cable with the USB connector of your computer.

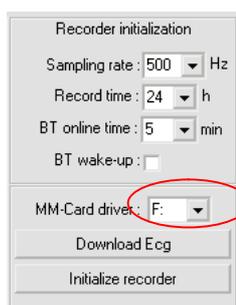
There is no use to install specific drivers when using Windows 2000, NT, XP or Win7/Win8. The system will detect and install the ECG recorder automatically.

Memory Drive configuration

When connecting the ECG recorder with the computer Windows will show an explorer window which includes the used drive letter (F: in this example)



Please choose the same drive letter inside the recorder initialization menu. The **Download ECG** button should be active now. If not, please restart the software.

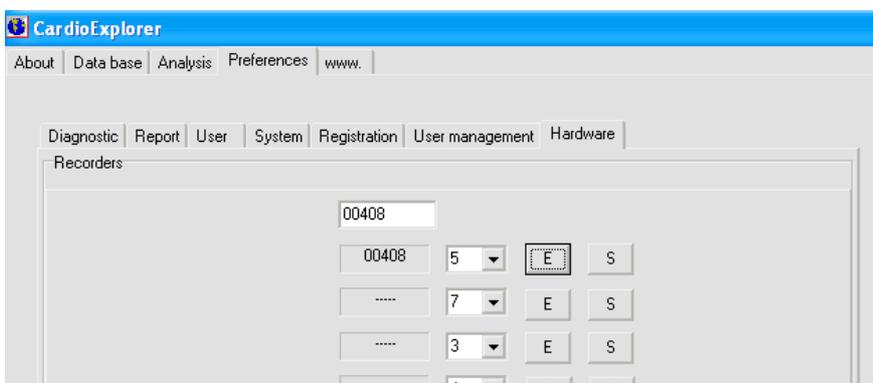


Bluetooth configuration

Ensure that your ECG recorder is switched on by plugging in a electrode cable and do a right mouse click onto the Bluetooth Icon inside the right side of your Task-Line and choose "Add device". Follow the Bluetooth menu and pair the device, the pairing key is 0000 (4xZero).

After installation the Bluetooth menu will show the used incoming and outgoing com port for this recorder.

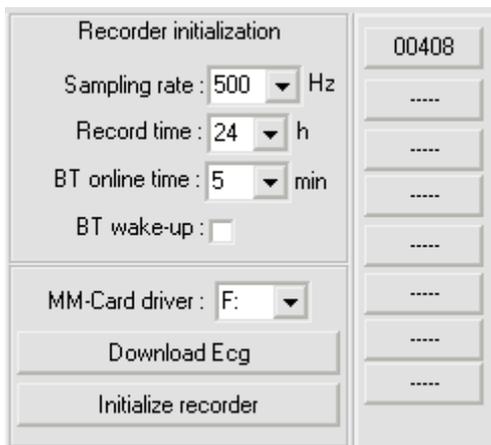
Note the outgoing com port and run CardioExplorer ? Preferences ? Hardware and click to "E" to edit the first recorder line



Type in your recorder serial number and choose the outgoing com port from recorder installation. Press "S" to save the entree.

If you have more recorders please do the same steps again for each recorder.

When you have configured all your recorders you can go back to the database sheet and you will find your serial number inside the online control menu:



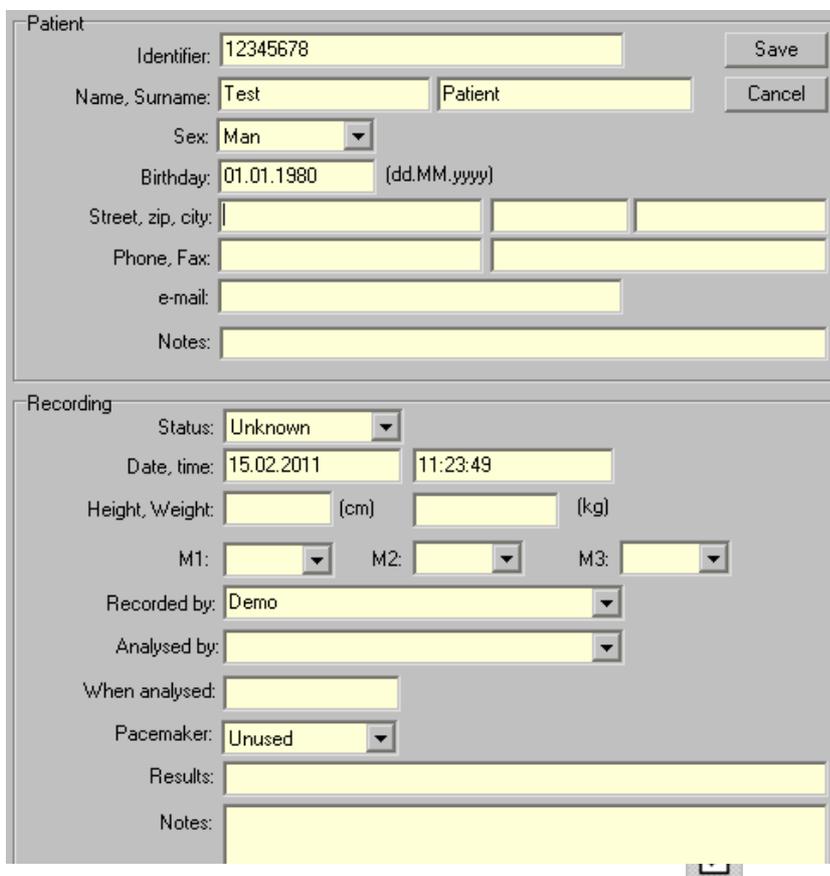
3. Start Recording

Preparing the ECG recorder

Run CardioExplorer software and connect the Multi-ECG recorder with the USB cable to your computer.

Choose the recording time you like to have (in actual version 24h is default)

Click onto the button  **New patient, recording** and fill in the patient information:



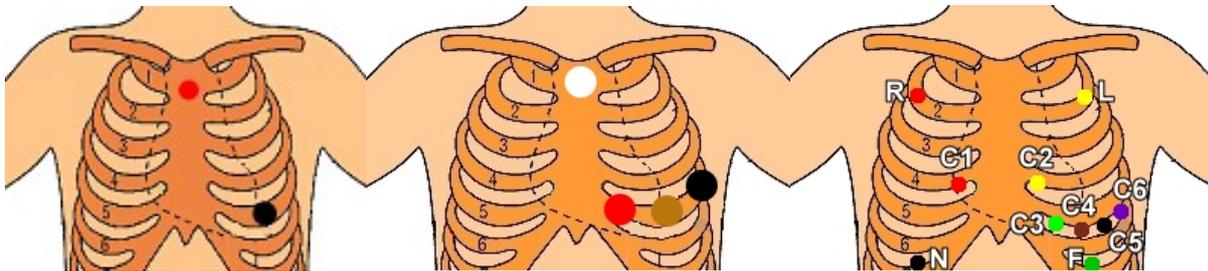
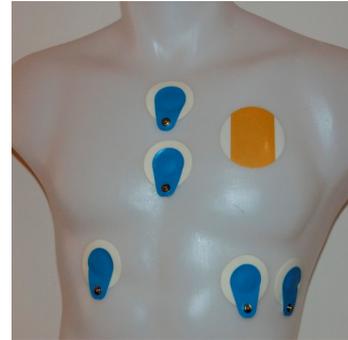
The screenshot shows two main sections: 'Patient' and 'Recording'. The 'Patient' section includes fields for Identifier (12345678), Name (Test), Surname (Patient), Sex (Man), Birthday (01.01.1980), Street, zip, city, Phone, Fax, e-mail, and Notes. The 'Recording' section includes Status (Unknown), Date, time (15.02.2011 11:23:49), Height, Weight, M1, M2, M3, Recorded by (Demo), Analysed by, When analysed, Pacemaker (Unused), Results, and Notes. Buttons for 'Save' and 'Cancel' are visible in the Patient section.

Save your new patient by clicking to **Save** or  **Edit Recording**. The data are saved into the database and onto the Flash Memory inside the recorder.

Mounting the recorder

Clean the skin at the positions of the electrodes (belonging to the electrode cable you are using, see below) and the Pad for the recorder very properly and mount the electrodes and the recorder pad.

Please note, that the quality of your recognition belongs directly to the quality of your skin preparation. The skin should be lean and hairless.



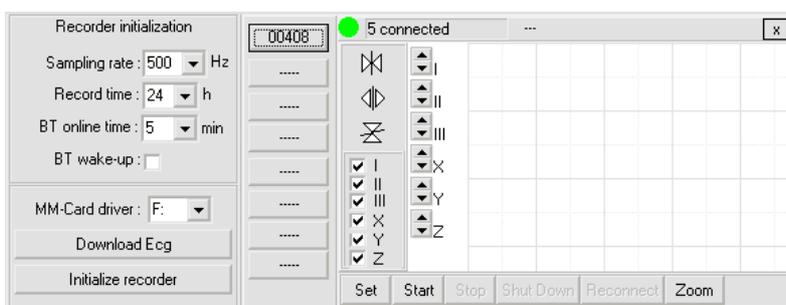
Remove the yellow paper from the recorder Pad and mount the recorder on it.

Connect the clips from the electrode cable with the electrodes and plug the electrode cable into the recorder.

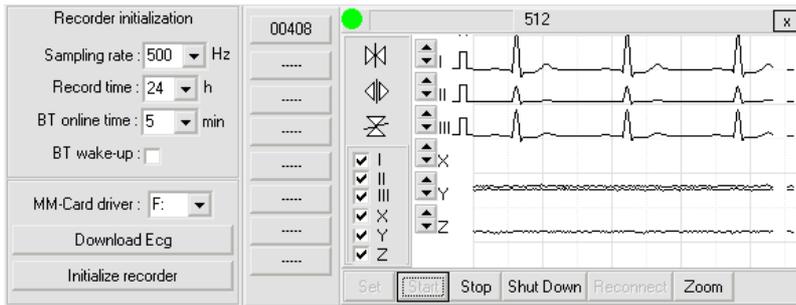
As we use such short electrode cables, there is no need for additional fixations. The system is now ready to start.

If your recorder is configured for "Autostart" the recording will start automatically and you should hear 2 short beeps. When hearing a long beep (5 seconds) the recorder contain data which are not downloaded – in this case you have to download the data first and after that you can plug the electrode cable again to the recorder.

If your recorder doesn't have "Autostart", please run CardioExplorer and inside database please press to the button with your recorder serial number:



Inside the coming up online control window press "**Start**" to start the recording



The recorder will beep 2 times and inside the online control window you will see the ECG signal together with the accelerometer signals (outher when using a 10 leads cable – in this case you will see 6 ECG channels).

Use the “**Zoom**” button to increase the the Online control window and after that the “**Normal**” button to come back to this size.

Check the quality of the ECG data and if everything is OK the patient can leave, and if you havn't a good quality you can replace the electrodes.



The recorder pads are produced of bio compatible materials that makes them eudermic. It is possible that the skin of sensitive patients may be irritated. The patients should be clarified about this.



The electrodes and pads are designed for single use only. Do not use them for more than one recording and dispose all accessories according to national laws and guidelines.



The recharchable batteries should be loaded after every use. Please connect the recorder to the computer or external power supply for charging until you can see the green light indication.

Dismounting the recorder

Unplug the electrode cable from the recorder and remove all electrode connectors and electrodes. Take off the recorder together with the adhesive pad and remove the adhesive pad from the recorder.

Clean the patients skin.



Run CardioExplorer software and connect the recorder to the computer by using the USB data/charging cable. Click to the button "**Download ECG**" to store the recorded ECG data into the database.

The file is now ready for analysis.

For handling the recorder please refer also the recorder manual.

4. Quick Guide

In 6 steps to your successful ECG-Result

Step 1: Run CardioExplorer and save the new patient information to the recorder

Step 2: Mount the recorder together with the electrodes on the patients body and plug inn the electrode cable

Step 3: Connect the recorder via Bluetooth and press the Start button

----- 24 h later -----

Step 4: Dismount the recorder and the electrodes

Step 5: Connect the recorder via USB cable to the computer

Step 6: Run CardioExplorer software and download the data.

The data are ready for analysis

5. CardioExplorer Analysis-Software

During the development of the CardioExplorer Analysis-Software special attention was given to an easy intuitive and individual operation as well as to a very clear and structured designed user interface. With purchasing the CardioExplorer Software you received an efficient tool that combines all relevant functions of a functional analysis software.



Please note that the integrated analysis in this software represents only a help for your evaluation. The automatic analysis is not designed to share the results without control and to create a report based of the automatic analysis only.

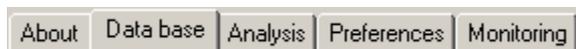
The data must always controlled by you and corrected if necessary.

The Mouse allows comfortable operation of the software. All functions are described in detail on the following sides. It is also possible to handle selected functions with the keyboard. The according key combination is also given in the following detailed description. For easy and fast finding of key combinations a yellow sign is used as prefix.

Example:  <CTRL> + <a>

For key combinations it is necessary to press the first key and hold it while the second key of the combination separated with the "+" symbol is pressed.

The software of CardioExplorer consists of four different submenus. To switch between these menus the submenus can be selected by clicking on each register at the upper left corner of the display. Also the register can be switched by pressing the selected key combination.



The four submenus are:

- | | | |
|----------------|---|-----------------------------------|
| 1. About |  | <CTRL> + |
| 2. Data base |  | <CTRL> + <d> |
| 3. Analysis |  | <CTRL> + <a> |
| 4. Preferences |  | <CTRL> + <o> |
| 5. Monitoring | | (not available in actual version) |

About – Start page

After starting the CardioScout Software the About start page appears on your display. On this page you find the address of your specialist dealer. For questions of all kind, please contact this address.

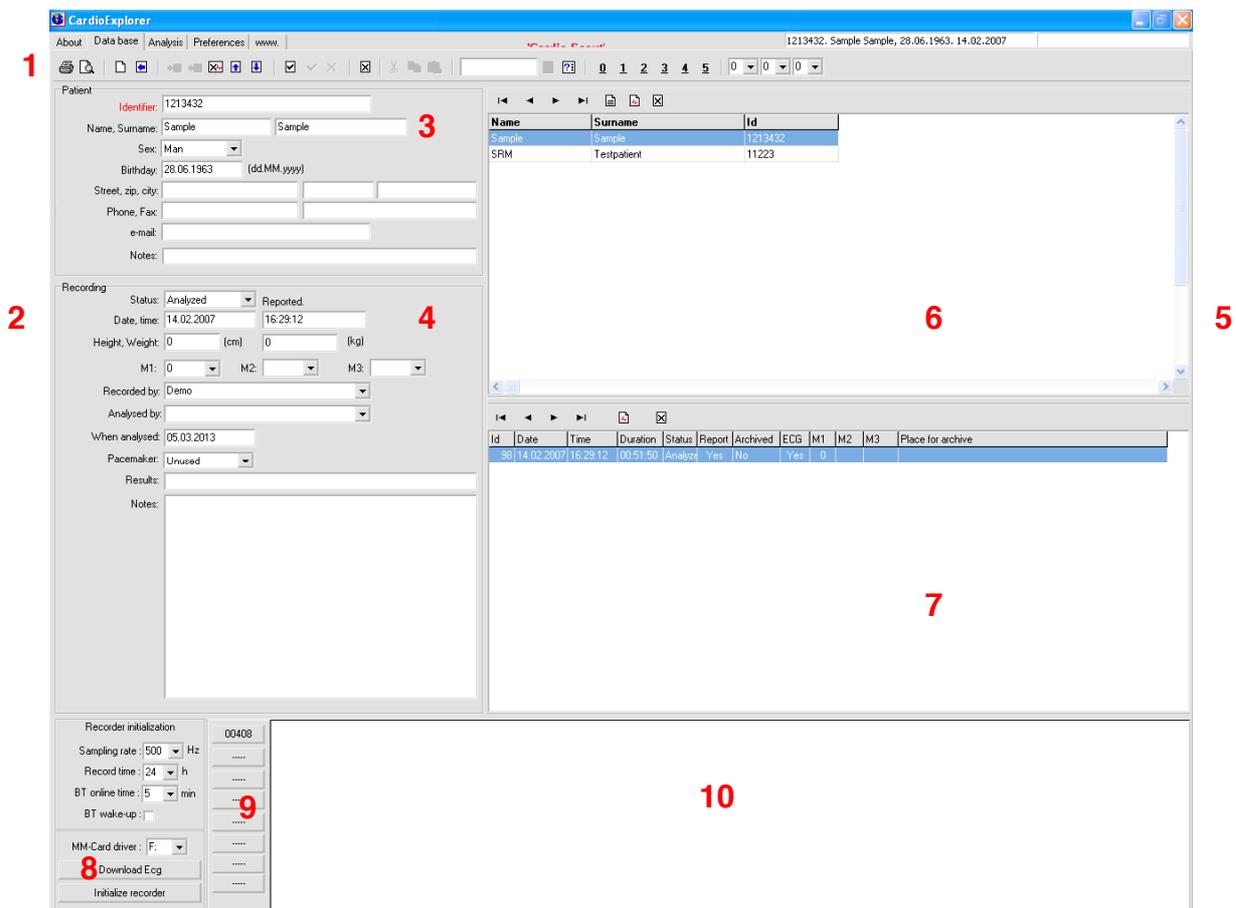
The version number of your software is also displayed in this submenu.



This screen is only for information fade out automatically after 3 seconds.

Database

The data base form is used for storing the patient data and to display the corresponding record of the medical examination. The data base enables you to read ECG data set out of the recorder, to start the analysis, to store recording data and display them whenever necessary.



The database sheet consists of the following parts:

- 1** Control menu
- 2** Data mask
- 3** patient mask
- 4** record mask
- 5** Data overview
- 6** patient list
- 7** record dataset list
- 8** recording parameter
- 9** Bluetooth control
- 10** online control / recorder control

Control menu



The control menu consists of buttons for navigation inside the data base form. The buttons are separated to their different functions:

1. Print

- | | | | |
|---|-----------|--------------------------------------|--|
|  | Print | open the report generator |  <Strg> + p |
|  | Side view | shows the report from active session | |

2. Record control

- | | | | |
|--|----------|---------------------------------|---|
|  | New | includes new patient or session |  <n> |
|  | Load ECG | loads ECG data from MM-Card | |

3. Data controlling

- | | | | |
|---|-----------------|---|--|
|  | Archive | archives ECG data on a medium | |
|  | Reload | loads archived ECG data | |
|  | Delete ECG data | deletes ECG data (raw data). Patient information and reports are kept | |
|  | Export | exports ECG data | |
|  | Import | imports ECG data | |

4. Data set controlling

- | | | | |
|---|----------------|---|---|
|  | Edit | opens actual patient data set for editing |  <e> |
|  | Accept changes | accept changes and store them for current active data set | |
|  | Reset dataset | erase changes and set back to last saved data set | |

5. Data set controlling

 Delete deletes actual session  <Entf>

6. Text controlling

 Cut cut marked data and copy into clipboard

 Copy copy marked data into clipboard

 <Ctrl> +
<Ins>

 Paste insert data from clipboard

 <Shift> +
<Ins>

7. Search

 Text field search field for search term

 Search Text field search button for entered search term

 Search all opens patient data set to serch for all data fields

8. Filter functions session

 undefined shows all undifined sessions

 mounted shows all mounted sessions

 downloaded shows all downloaded sessions

 analyzed shows all analyzed sessions

 edited shows all edited sessions

 reported shows all reported sessions

9. Filter functions Patient data set

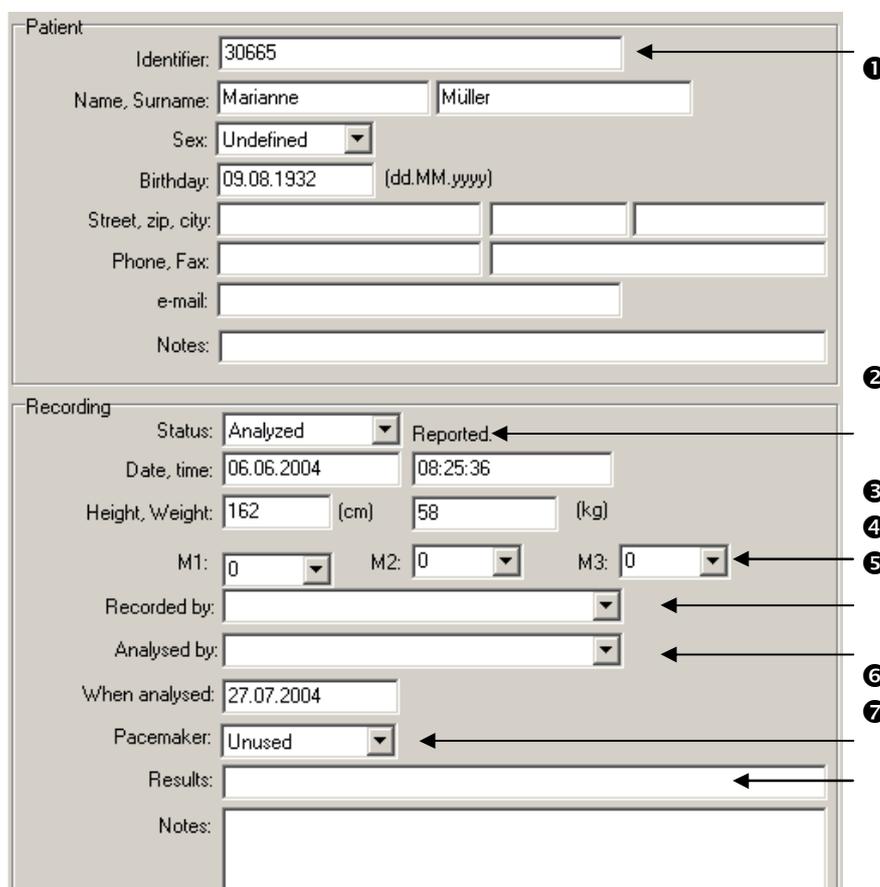
 Filter

filters the patient data in the light of the used filters inside patient data set

Data mask

Next to the detailed information about patients and the recorded data sets the data base formulary consists of two data mask parts – the patient mask and the record mask. The data masks are used for display, input and change of patient and record data's.

For safety reasons the data inside the data mask are protected from clearing. Without clicking the EDIT button no erasing or changing is possible. The EDIT button enables the changing of the data inside the mask. Data inside the mask are protected against accidental changes. To insert the data's of a new patient the button "NEW"  or pressing the key  <n> are used. After creating a new patient it enables the operator to insert patient and recording data via data mask.



The image shows two data mask forms: 'Patient' and 'Recording'. The 'Patient' form includes fields for Identifier (30665), Name, Surname (Marianne Müller), Sex (Undefined), Birthday (09.08.1932), Street, zip, city, Phone, Fax, e-mail, and Notes. The 'Recording' form includes Status (Analyzed), Date, time (06.06.2004 08:25:36), Height, Weight (162 cm, 58 kg), M1, M2, M3 (all 0), Recorded by, Analysed by, When analysed (27.07.2004), Pacemaker (Unused), Results, and Notes. Numbered callouts 1-7 point to specific fields: 1 points to Identifier, 2 to Notes, 3 to Status, 4 to Date, time, 5 to M1, M2, M3, 6 to Recorded by, 7 to When analysed.

Some of the input fields use the advantage of a drop down listing . When pressing the selecting button  a listing drops down with pre-selected field inputs. One mouse click is taken over the selected field input.

- 1 Input of patient ID.



It is necessary to enter patient ID, first name and last name to secure the correct assignment after storing the data!

- 2 The Status of the current active record is automatically selected by the system software. Sometimes it might be necessary to change the status of a record manual.

Following status information's can be selected:
unknown, mounted, downloaded, analyzed and edited.

- 3 Further Status information for later filter functions are separated into according groups.
- 4 Selection of the operation person, who made the examination. All names in this drop down list are inserted in the register Preferences.
- 5 Selection of the person, who controlled the analysis. All names in this drop down list are inserted in the register Preferences.
- 6 Input field for possible pacemakers
Following input's can be selected:
unused, demand and on trial
- 7 Input field for quick result

The keys  <TAB> and  <Shift>+<TAB> are used to switch to the next field and to the last field. Additionally to the  <TAB>-key the  <ENTER>-key is used to switch to the next field.

Data overview

In the upper right part of the data base form there is a list of all saved Patients. Below this part all recorded data sets of the current active patient are listed.

The screenshot displays two tables in a software interface. The top table lists patients with columns for Name, Surname, and Id. The bottom table lists recorded data sets with columns for Id, Date, Time, Duration, Status, Report, Archived, ECG, M1, M2, M3, and Place for archive. Callouts 1-4 point to navigation and action icons in the table headers.

Name	Surname	Id
SampleName	SampleSurname	170501
Paul	Richter	10002
Sarah	Richter	10003
Eva	Junge	1004
Jan	Müller	132413
Uwe	Haertig	21255
Felix	Richter	10001
Hartmut	Frank	12345
Sabine	Lieglein	0157759021
Anna-Lena	Firzlaff	070591
Marianne	Müller	30665

Id	Date	Time	Duration	Status	Report	Archived	ECG	M1	M2	M3	Place for archive
15	06.06.2004	08:25:36	00:00:00	Analyzed	Yes	No	Yes	0	0	0	

1 Navigation list for patient registration

-  - move to first patient listed
-  - move to previous patient listed
-  - move to next patient listed
-  - move to last patient listed
-  - create new patient
-  - create new record data set
-  - delete current active patient and all records that belong to this patient

② Patient listing:

Id	- patient ID
Surname	- last name of the patient
Name	- first name of the patient

③ Navigation list for record registration

	- move to first record data set
	- move to previous record data set
	- move to next record data set
	- move to last record data set
	- create new record data set
	- erase current active record data set

④ Record data set listing:

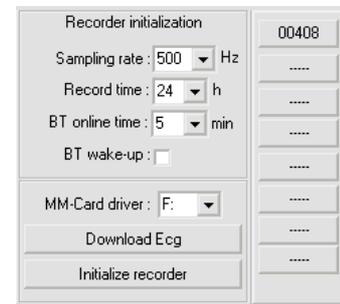
Current	- displays which record data set is active and in use
Id	- automatically created, not changeable unique ID number for each record data set
Date	- recording date of record data set
Time	- starting time for record data set
Duration	- duration time
Status	- status of record data set
Report	- report is generated? (Yes / No)
Archived	- ECG data archived? (Yes / No)
ECG	- ECG data are available or deleted
M1, M2, M3	- used filter
Place for Archive	- place for archive

For switching between patient and record data set listing the key  <TAB> is used.

Recorder controlling

The recorder controlling is used to

- to set the recording parameters
- to initialize the recorder
- download recorded data
- online control



Following functions are available:

Sampling frequency - Select sample frequency between 125 and 2000 Hz.

500 Hz is the default sampling rate for CardioExplorer!

Record time - to define the recording time (actually max. 24h)

BT online time - defines the time until BT is switched off

BT wake up - defines, if the Bluetooth modul inside the recorder will restart after placing a patient marker

MM-Card Driver - defines the drive letter the recorder is using

Download ECG - to download the stored ECG data

Initialize recorder - to save the actual patient and recording information into the recorder

Accomplishment of ECG recording

Before starting a new recording you should charge the battery and you have to connect the recorder via USB cable to the computer.

Patient data input

1. Create a new patient in the data base of the analysis software by pressing the button  **New patient, recording** or select one of the existing patients listed.

2. Insert all necessary patient data in patient mask. In case of selecting an already existing patient ID, the patient's data of the patient is automatically written into the open fields and the Cursor moves directly to the record mask.
3. The record mask enables the selection of specific record data which are relevant for the start of the CardioScout Recorder.
4. After all inputs are done the button **EDIT Recording** or **Save** will save your entrée.
5. Disconnect the recorder. It is now prepared to start a recording

Start recording

After mounting the system you can plug the electrode cable into the recorder for starting a new record. Please be careful not to damage the sealing ring.

The recorder will beep one time (initialization beep) and will now be ready for a Bluetooth connection. Press the Button with the serial number to connect the recorder. In the upcoming online control window press "Start" to start the recording – recording starts and you can see the online data on the screen.

That's it – the patient can leave...

When having problems with the quality you should remove the electrodes and clean the skin again, or choose other positions for the electrodes.

Download data

Run CardioExplorer software and connect the recorder via USB cable to the computer. Click to the button **Download ECG** to store the recorded ECG data into the database.

The file is now ready for analysis.

Erase patient or recording

1. To erase one single recording data set from the data base select the recording data set. Then erase the currently active record set by:
 - Click on the Button "DELETE CURRENT RECORDING" button menu bar

- Or press the right mouse button and “DELETE RECORDING”  in the function list that appears,
 - Press the key  on your keyboard
2. To delete one patient together with all attached record data set from the data base select the patient in the upper part of the table. Then erase the currently active patient by:
- Clicking on the button “DELETE CURRENT PATIENT AND ATTACHED RECORDINGS”  in the menu bar of the upper table
 - Pressing the right mouse key and select “DELETE PATIENT”  or,
 - Press the key  on your keyboard.

Change patient data and record sets

1. Select the patient or the recording in the patient or record list.
2. Press the button “EDIT RECORDING”  in the menu bar.
3. Change the data's.
4. Press the button „POST EDIT“  to save the changes.
5. Press the button „CHANCEL EDIT“  to reset the input.

Search for a patient

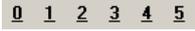
1. Use search input field  to enter the patient data. Enter patient ID, first name or last name of the patient.
2. After pressing the button “SEARCH”  the request is started

Filter functions

A large amount of filter functions is provided by the software to improve the overview for recording status and patients.

Buttons are used to activate the filter functions. To deactivate the filter function the button is pressed a second time.

Two different types of filters are distinguished:

Record status filter 

Record status filter are used to filter the record data and to obtain a better overview over current record situation of the patient. It is possible to display all patients in examination, or just patients with a analyzed record data set.

Only one record status filter is active at one time. It is not possible to activate two or more record status filters.

Patient status filter 

Patient status filter are used to organize the database into different groups of patients or sessions. The user should create a list of the individual allocation of the included markers (M1 to M3).

Export patient data

Data export is used to transfer patient and record data to external systems for data securing reasons.

1. Select the record data you want to export.
2. Press the "EXPORT"  button in the menu bar
3. Enter saving location into dialog window and start export by pressing the **SAVE** button in the dialog window.

Import patient data

Data import is used to transfer patient and record data from external systems in CardioExplorer data base.

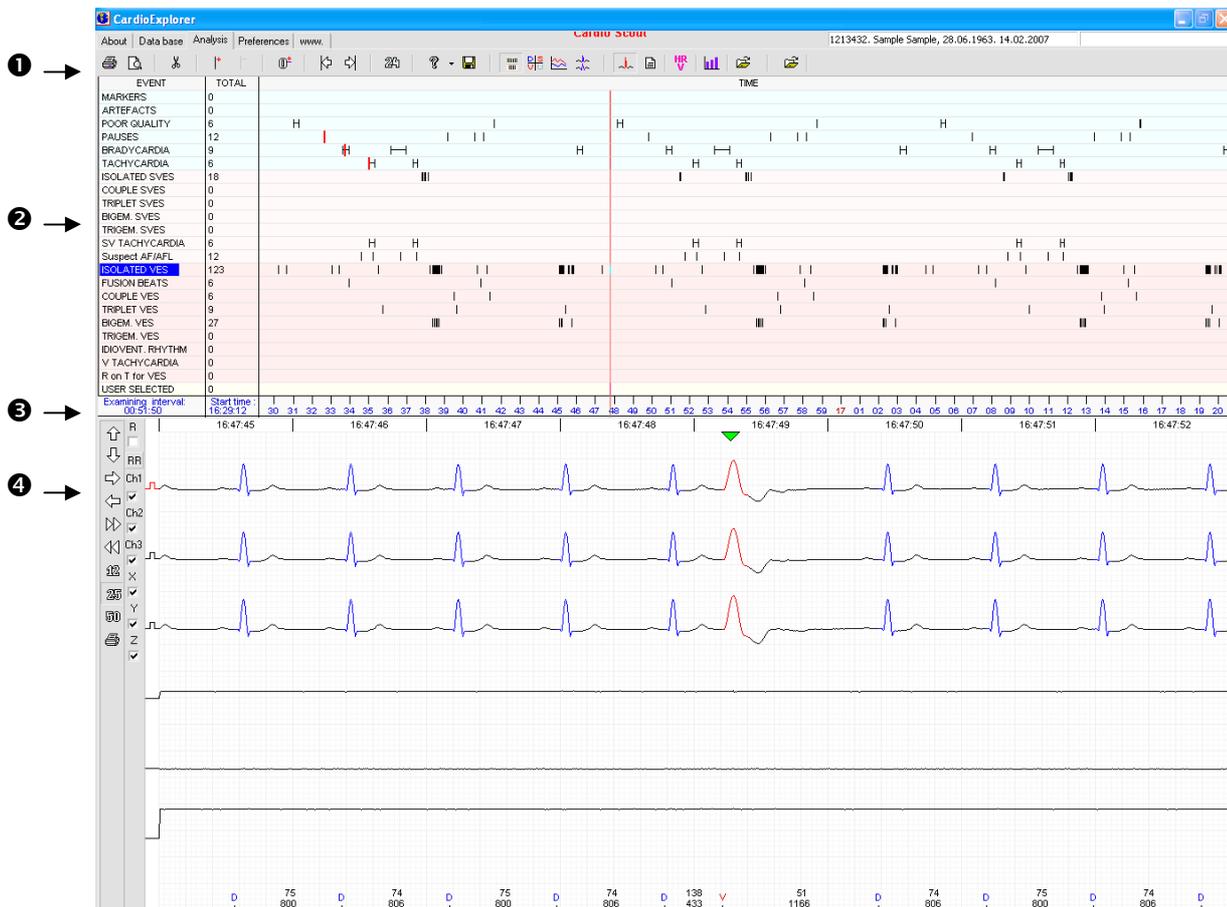
1. Press the **IMPORT**  button in the menu bar
2. Select record name in dialog window and start import by pressing the **OPEN** button in the dialog window.

Analysis

The CardioExplorer Analysis tool supplies a very clear and structured display of all examination data. The great selection of different displays, such as event report, QRS-Complex or heart rate variability diagram enables a meaningful data display and eases the evaluation of the record data set.

Start analysis

1. Do a right mouse click onto a session and choose **Analysis**, or
2. Double click a session, or
3. Click to the sheet **Analysis** in the upper left side



The screen layout of the Analysis tool is separated into four parts:

1. Control menu bar

- ② Analysis window
- ③ Time scale
- ④ Signal window

Analysis- and signal window are separated with the time bar. The time bar is used to display the time period of examination, the recorder start time and a time scale of the examination. When activating the time bar by mouse the mouse symbol changes to an arrow. With activating the mouse symbol by pressing the left mouse key a red time courser appears in the analysis window. The signals recorded at the position of the time courser are displayed in the signal window below.

Control menu bar



The control menu bar consists of following function and navigation tool:

	PRINT REPORT	- Print Analysis in report form
	PRINT PREVIEW	- Preview Report layout on screen
	DELETE	- delete all marked events
	INSERT MARKER	- Insert own marker in the provided line of the event overview.
	DELETE MARKER	- Delete one of the own set markers set with the INSERT MARKER function.
	EMPTY ROW	- Hide and unhide selected event lines without any event in the record data set.
	PREVIOUS MARKER	- Move to previous marker
	NEXT MARKER	- Move to next marker
	COMPLETE EXAMINATION	- Displays the complete examination
	RUN ANALYSIS	- Start new analysis (presetting possible)
	SAVE	- Save analysis-result

	EVENT-OVERVIEW	- Overview of all events
	QRS-TEMPLATE	- Overview of QRS-templates
	TREND	- Displays HR, RR, St and JT trend
	ECG-OVERVIEW	- Overview of complete ECG record data set
	ECG-WINDOW	- Displays a selected window of ECG record data set
	VERBAL INTERPRETATION	- Displays the verbal interpretation
	HEART RATE VARIABILITY	- Displays the results of the heart rate variability
	HYSTOGRAM WINDOW	- Displays the main events in a histogram
	Kasper Helene, 30.06.20. Aufgezeichnet : 26.03.01. 150 [Hz]	- Status field, display the patient name, date of birth, date of record and sample frequency

How to do an Analysis:

When the recording is done – after finished recording time - the Recorder is removed from the patient. Connect the recorder with the USB cable to your computer.

Press button **Download ECG** and the recording is transferred into data base to the according patient. The window “Reading ECG data” indicate the current status of the data transfer.

After the transfer is finished the Analysis appears as new recording in the recording list with the status “downloaded”.

By clicking onto the right mouse key placed on one of the listed recordings a drop down list appears. The function “Analyze” is starting the Analysis. The function “Show result” displays the last saved analysed recording.

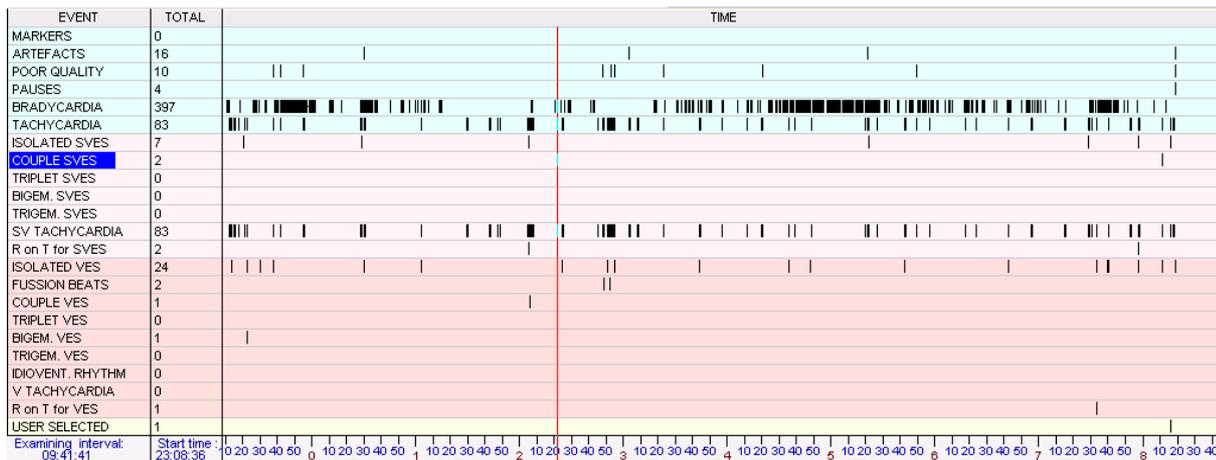
With double-clicking onto the left mouse key placed on one of the listed recordings, the selected recording is analysed.

The event overview displays now all relevant events, while the window below displays the first ECG-Readings of the examination.

Event Overview



The event overview is a very clear display of the ECG relevant events



The events are separated in four colored areas:

- Green: all events existing in a record data set like set markers of record, artifacts, poor quality signals, break in examination and amount of bradykardia and tachykardia
- Pink: all supraventriculare events
- Violet: all ventriculare events
- Yellow: all set markers of analysis

Presenting Events

The event overview is used to display all recognized results as vertical bar in one specified line. In case one specified event is repeatedly occurring for a longer period it is framed as a start and stop bar, connected with a horizontal line.

The column „TOTAL“ indicates the amount of detected events. The button is used to improve the structure of the overview and all lines without detected event are hidden. Pressing the button again unhide the hidden lines.

Maximum values of BRADYKARDIE and TACHYKARDIE are highlighted as a bigger red bar as well as the longest break is indicated this way.



Search for events

1. With pressing the left mouse button on the line with the specified event the event is marked. 
2. The function keys „MOVE TO PREVIOUS MARKER“  and „MOVE TO NEXT MARKER“  are used to jump from one specified event to the next.
3. Another possibility is to select a specific event directly with the left mouse key in the event window. Only one specific event is selected at the time and with pressing the left mouse key the cursor jumps to the next event.
4. Pressing the  Space-Bar of the keyboard is also a possibility to jump from event to event.

The signal window is used to display the corresponding ECG Signal that is marked with a green triangle.



Insert

and delete own markers

During the complete analysis it is possible to insert and delete own markers to find special events faster.

1. Move cursor to the position of the recording, where a marker should be inserted.
2. Select the button “INSERT MARKER” , and a new marker is added.
3. To delete one of the own inserted markers use function keys „PREVIOUS MARKER“  or “NEXT MARKER”  to select the marker and press the button “DELETE MARKER”  to delete the marker out of the event line.

Delete all markers in one event line

1. Select the event line and mark the line with a mouse click.
2. The button “DELETE”  does erase all markers in this line.

Select single timeframes

Instead of selecting one complete examination it is possible to select one specific part of the examination. The selection works simply by clicking and holding the right mouse key inside the event overview while moving the mouse and generating a selection window. The event overview is now zooming into this part. For displaying the complete examination the  button is selected with one mouse click.

Time bar

The analysis- and signal window are separated by the time bar.



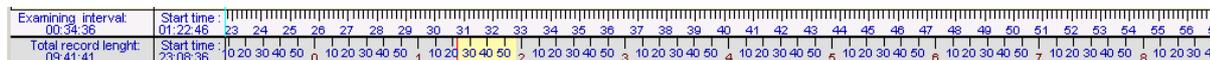
The time bar is used to display the time of examination and to navigate within the examination.

The left field of the time bar indicates the period of examination, the recorder start time follows and rest of the time bar is used for a time scale of the examination.

When activating the time bar by mouse, the mouse symbol changes to an arrow. With activating the mouse symbol by pressing the left mouse key a red time cursor appears in the analysis window. The signals recorded at the time of the time cursor position are displayed in the signal window below.

The time bar is used to scale the analysis window. Possible scaling are the complete examination as well as the specific periods marked with the mouse symbol. The imaging allows hour, minute and second scaling.

Holding the right mouse button while cursor is used inside the analyze window allows to select a period by moving the mouse, keep pressing the button. This way of marking an examination period creates a second time scale under the first one. This new time scale indicates the exact time of examination of the period marked.



The second lower positioned time scale still indicates the complete examination time. The yellow marked period is displayed in the analysis window.

The first higher positioned time scale displays the selected part of the analysis window. This makes navigating inside the ECG examination and still keeping an overview extremely easy.

For navigating inside the examination use the mouse or the function keys of the signal window. (v. chapter 3.3.4).

For navigation, the second lower positioned times scale is used to move the selected period forwards and backwards. The mouse symbol is placed on the time scale. With one mouse key pressed it is possible to move the yellow marked period to both sides. The left mouse key is used for slow continuous scrolling and the right mouse key is used to jump in one mask long steps.

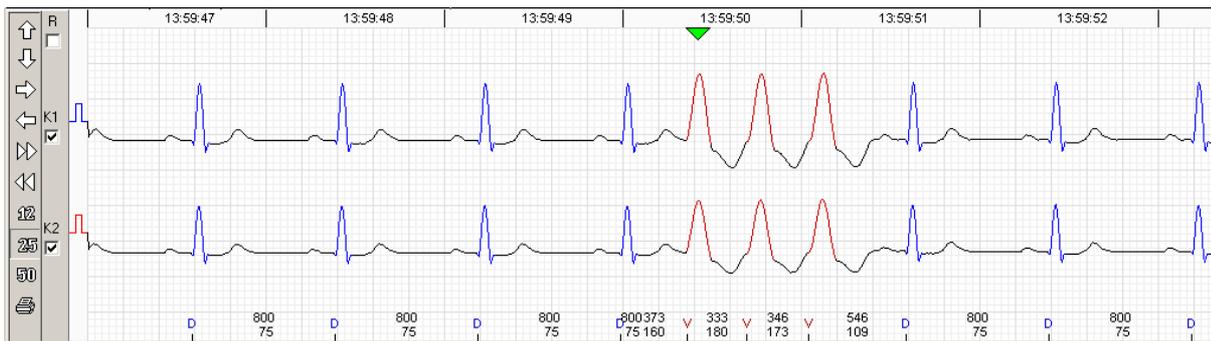
The first higher positioned time scale is scaling the part of the analysis window that has been selected. When activating the time bar by mouse, the mouse symbol changes to an arrow and the red time cursor appears. This cursor indicates the time of the ECG signal imaged in the signal window below and it can be moved in the yellow marked period only.

With activating the mouse symbol by pressing the left mouse key a red time courser appears in the analysis window. The signals recorded at the time of the time courser position are displayed in the signal window below.

ECG-Window



In the ECG-Window a section of the ECG recording is displayed.



The time bar at the upper border informs exactly about the actual position of the recording time.

At the lower border, the rhythm of the heartactivity is been displayed in milliseconds and in frequency [Hz].

Following functions are available:

-  - extend amplitude
-  - minimize amplitude
-  - move to next page
-  - move to previous page
-  - automatically upward run throught the recording
-  - automatically downward run throught the recording
-  - horizontal display with 12mm/s
-  - horizontal display with 25mm/s

-  - horizontal display with 50mm/s
-  - print-out of ECG segment
-  - selection of measurement frame
-  - switch to display first channel
-  - switch to display second channel

Optimal display

The function keys for adjusting the amplitude   and the paper feed rates    enables an individual signal display. User selected pre-selection of the signal adjustment enables an individual handling of the signals. It is also possible to display only one selected ECG channel  .

Image of Analysis

There are different possibilities to image the analysis.

Use of function keys :

- The function keys   are used to jump one page backwards and one page forward in the signal window.
- The function keys   are used to generate an automatic page feed.

Use of mouse:

- To select and move signal window to a specific point of record, press left mouse key on selected position on the time bar. While holding the left mouse key scrolling through the complete time bar is possible.
- Instead of displaying the complete examination, selected parts can also be displayed. With holding the right mouse key in the event window and moving, a new time window is defined. The event window now images the events of the selected time window. The button  is used to re-enter the record event window for the complete record data set.

Measurement frame

There are two methods available for measuring the ECG signal:

1. Move the mouse cursor to one edge of a segment, which should be measured out. While pressing the left mouse button and moving the mouse, a rectangular red colored frame appears. The corresponding values of the amplitude/mV (Y-scale) and time/ms (x-scale) are been displayed. The red frame will disappear with releasing the mouse button.
2. It is also possible to compare different signals in amplitude and timeshift. For this option just select the R  -field that is placed in the function bar and proceed as described in step 1. The red frame remains on the display and can be moved with the mouse. Unselect the option R  to deactivate the frame or with a double click onto the right mouse key.

Reclassify signals

It is possible to re-classify single signals within the ECG-Window. Below each QRS-complex you find the classification of the detected signal.

Following classification codes are used:

D – Domain Normal, normal inconspicuous signal

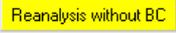
S – Supraventrikular event

V – Ventrikular event

A – Artefact

U – Unknown event

To re-classify a QRS-complex just point at the signal with the mouse cursor and click right mouse button. A selection list window appears on the left and by simply selecting one of the listed classification group the QRS-template is immediately re-classified into the selected group.

In the control menu bar one flashing signal  indicates a necessary re-classification while the report must be updated with your changes. You can reclassify several events and do the Reanalysis at the end, there is no need to do a Reanalysis on every Reclassification you are doing.

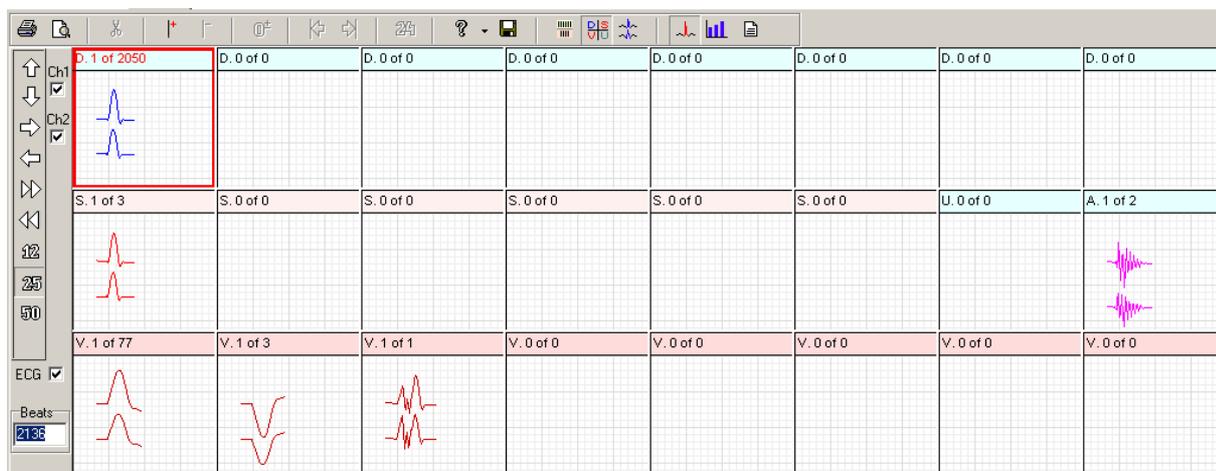
Choose event examples or include your own text

You can mark sequences as examples for the report by pressing the right mouse key between two classified QRS complex. A small menu appear and you can choose one of the included example names or type in your own comment:



When entering your comment a marker is placed automatically inside the user selected marker line, so that it will be easy for you to find this position again.

QRS-Templates



The left side of the QRS-template display is used for the control menu bar.

Following functions are available:

-  - extend amplitude
-  - minimize amplitude
-  - move to next QRS- template of the selected group
-  - move to the previous QRS-template of the selected group
-  - automatic upward run of all QRS-templates in the selected
-  - automatic downward run of all QRS-templates in the selected
-  - horizontal display with 12mm/s
-  - horizontal display with 25mm/s
-  - horizontal display with 50mm/s
-  - display of all templates existing in one selected or both channels
-  - if ECG is selected, the ECG-Window displays the current signal
-  - amount of all heart beats during the examination

All QRS-templates are classified and assigned to groups of same morphology. The amount of templates assigned to each group is displayed.

The groups are separated in the classes:

D – Domain Normal, normal inconspicuous signal

S – Supraventrikular event

V – Ventrikular event

A – Artefact

U – Unknown event

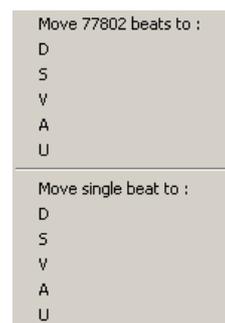
The Control menu bar enables a comfortable comparison of QRS-templates and if necessary it is possible to re-classify single QRS-templates and whole QRS-groups.

To reclassify single QRS-templates:

- Select the group of the QRS-template by clicking the left mouse key. Now the selected Group is framed in red. Move mouse symbol to the group of the new selected classification. With pressing the right mouse button on this selected classification group you can choose if all QRS-templates should be reclassified or only the current active QRS-template is re-classified. This procedure is used to re-classify single QRS-templates als well as complete groups of a new classification.

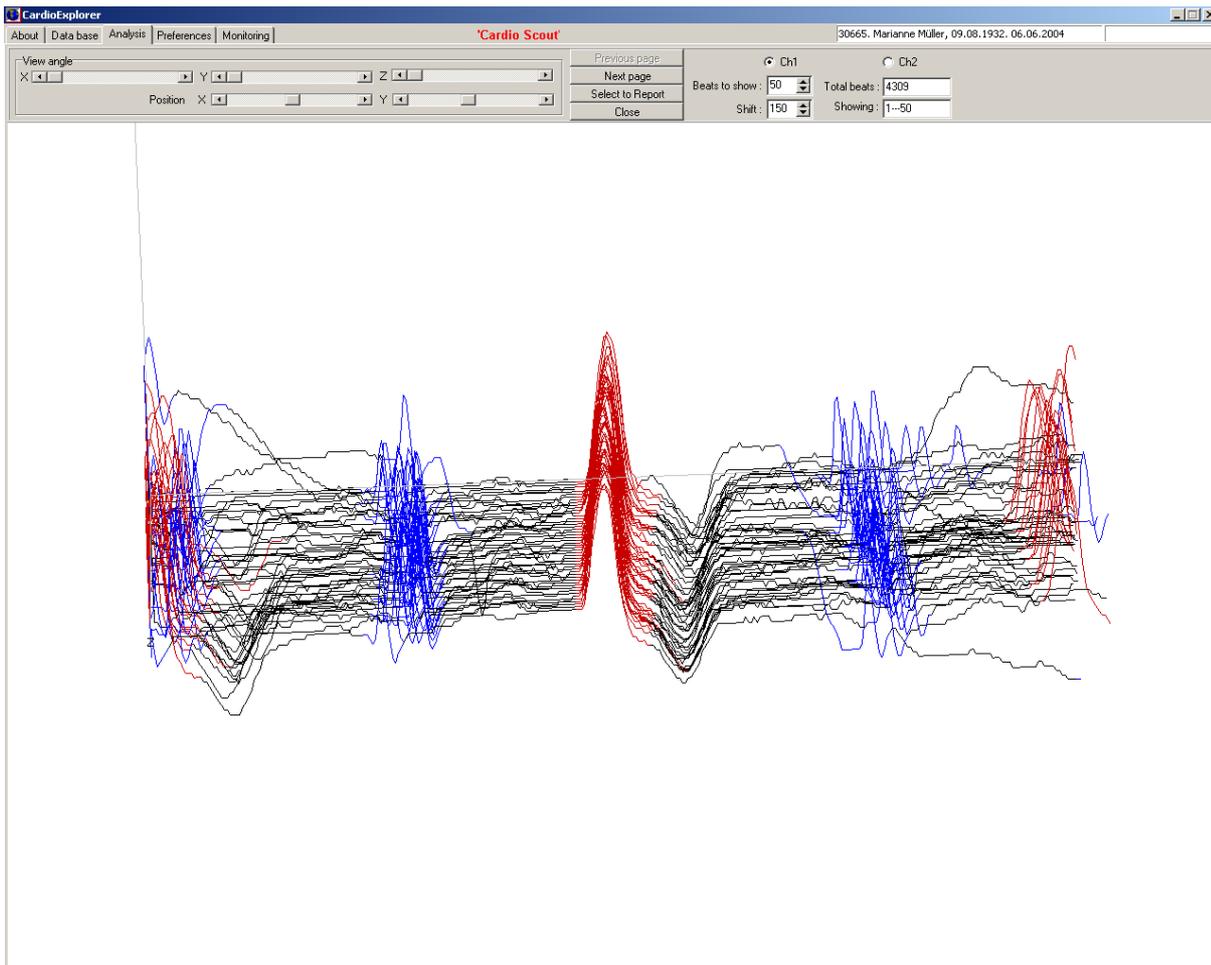


- You can also use the the small included menu to reclassify single beats, where you can move forward and backward and reclassify very easy the actual beat to D (Domain normal), S (Supraventricular), V (Ventricular), A (Artefact) and U (Undefined).
- Single QRS-templates can also be re-classified in the ECG signal window. To re-classify a signal QRS-template select one and press the right mouse key. After pressing the key the selection list on the left appears and you simply select one of the listed classification group. The QRS-template is immediately re-classified and assigned to the selected classification group.



3D Template viewer

If you select one template class with the left mouse key, you can jump into a 3D viewer by pressing the right mouse key:



Click and hold the left mouse key into the 3D picture and move the mouse to rotate the picture.

Click and hold the right mouse key into the 3D picture and move the mouse to change the zoom factor.

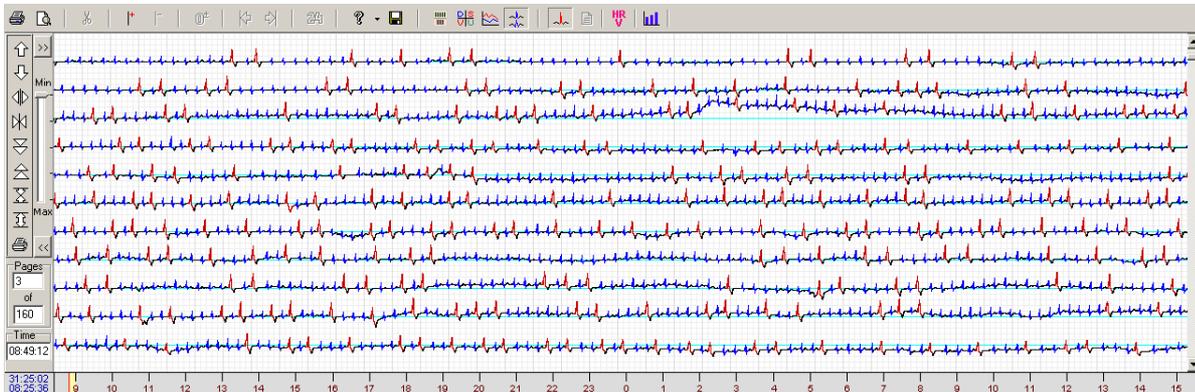
In the above menu you will find some more features to include or exclude information or beats, you can browse from page to page, change from channel 1 to channel two and you can select the actual picture for your later printout.

“Close” will end the 3D viewer and brings you back to the template menu.

ECG-Overview



The ECG overview realizes a clear display of the whole examination. All registered events are displayed in their corresponding colors.

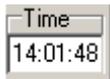


Following functions are available:

-  - extend amplitude
-  - minimize amplitude
-  - extend time scale
-  - minimize time scale
-  - move to next page
-  - move to previous page
-  - full screen image of complete ECG examination
-  - selection image of ECG examination



- indication of the current and the complete page number



- indication of the recording time at the current cursor position



- this menu allows you to start a automatic playback modus backward or forward.
The slide is to change the playback speed (Min = Slowest, Max = Highest)

While moving the mouse cursor over the ECG signals, the exactly related recording time is displayed in the "Time" window. If you select a signal by clicking the left mouse button, it will be displayed in the ECG window below. The selected signal is indicated by a green marking.

If you change to the event window, the red vertical cursor indicates the selected position. The other way around, a selected event in the event window is displayed in the upper left corner of the ECG overview.

By pressing the button  of the control bar, the ECG overview will be displayed over the whole window and the ECG signal window will be closed.

By pressing the button  of the control bar, the previous view is restored.

Cut off ECG data from analysis:

If you have sequences of bad quality ECG data you can cut off these data from analysis. Move the cursor to the beginning of the sequence you like to cut and press the right mouse key. Than move down and you will see that the ECG signal will green color, and the discoloration will follow your mouse cursor. Choose and set the end point by pressing the right mouse key again. The green colored area is now excluded from the analysis.

Press the Reanalysis button to overtake the changes into the outcome.

Trend-Window



With the Trend-Window, different analysis methods are possible:

- HR-Trend
- RR-Trend
- ST-Trend
- JT-Trend

With a "Trend" selection, displayed on the left side, the desired trend window can be selected. The function "Beats" allows to smoothen the trend signal over range of 1 and 20 beats. One beat means that the trend signal is calculated on the base of every heart beat. 20 beats means, that only every 20th beat counts for the calculation.

By changing the "Scale" the amplitude of the trend can be changed.

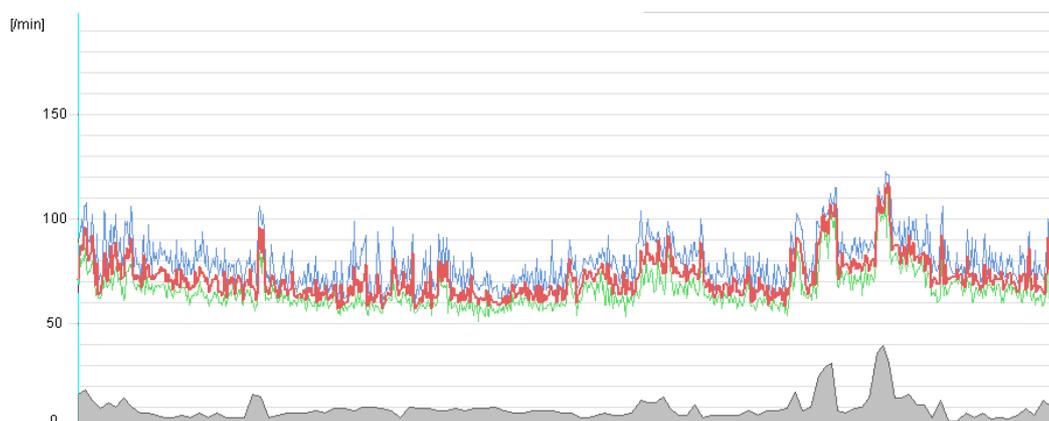
Trend1		Trend2	
<input checked="" type="radio"/> HR	<input type="radio"/> HR	<input type="radio"/> RR	<input type="radio"/> RR
<input type="radio"/> RR	<input type="radio"/> RR	<input checked="" type="radio"/> ST	<input type="radio"/> ST
<input type="radio"/> ST	<input type="radio"/> ST	<input type="radio"/> JT	<input type="radio"/> JT
<input type="radio"/> JT	<input type="radio"/> JT	<input type="radio"/> ...	<input type="radio"/> ...
Scale		Scale	
200		2000	
Beats		Time:	
4		08:49:12	
Average :			
95		-292	
Maximal :			
104		-116	
Minimal :			
89		-572	
Mean :			
63		-78	
Deviation :			
31			

The time window displays the recording time at the position of the mouse cursor. Furthermore the average-, maximal- and minimal value of the signal at the cursor position and the mean value of the whole recording time are indicated in different colors in the trend window.

Notice: For the report, only the current trend signals are printed as shown in the trend windows.

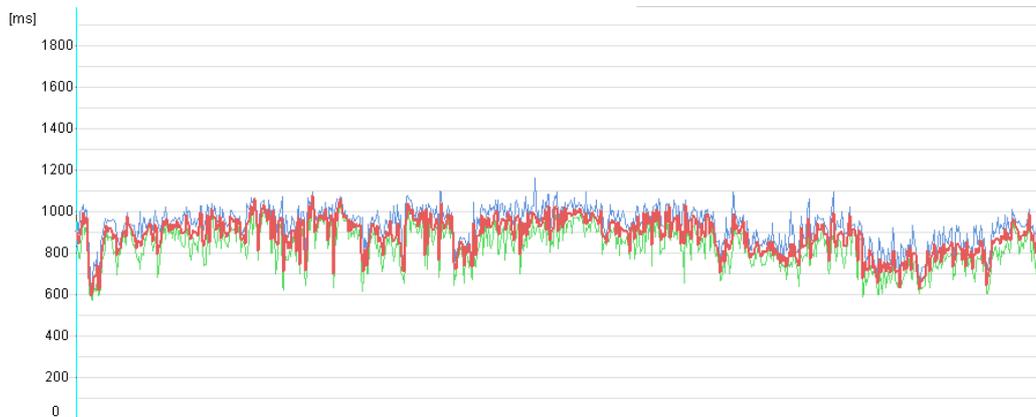
HR-Trend

The HR-window is imaging the heart frequency of the ECG record data set.



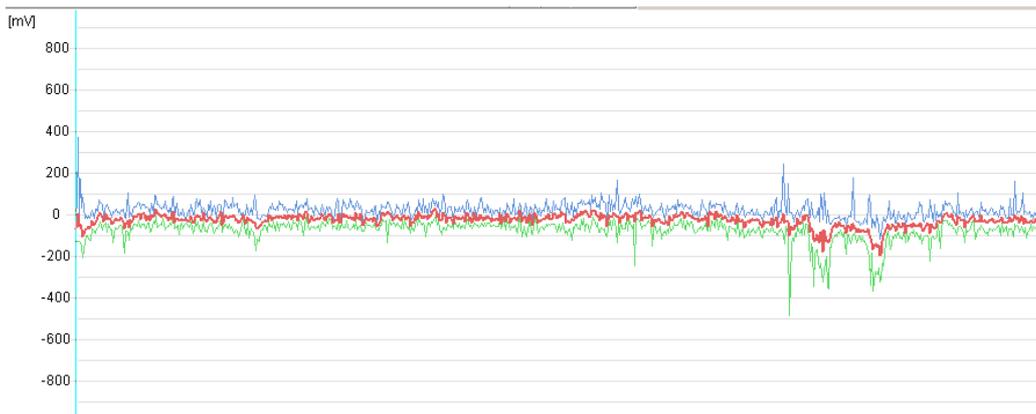
RR-Trend

The RR-window is imaging the RR-trend of the ECG record data set.



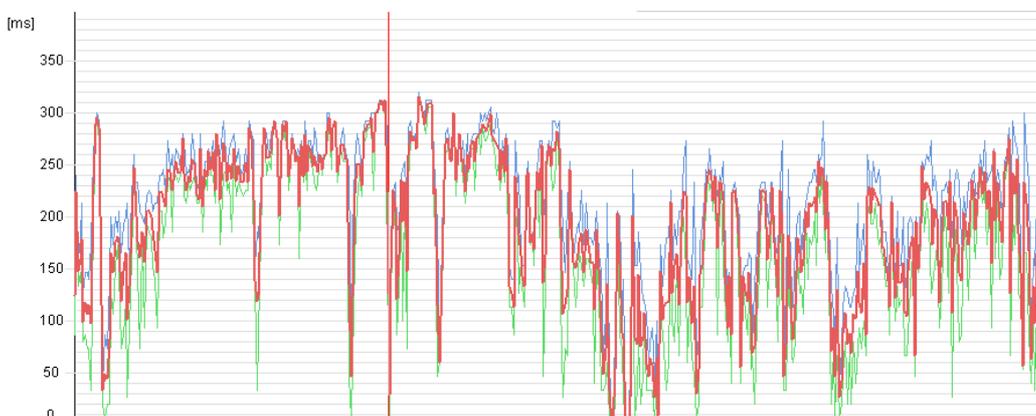
ST-Trend

The ST-window is imaging the ST-Trend of the ECG record data set.



JT-Trend

The JT-window is imaging the JT-trend of the ECG record data set.



Following functions are available for trendwindowing:

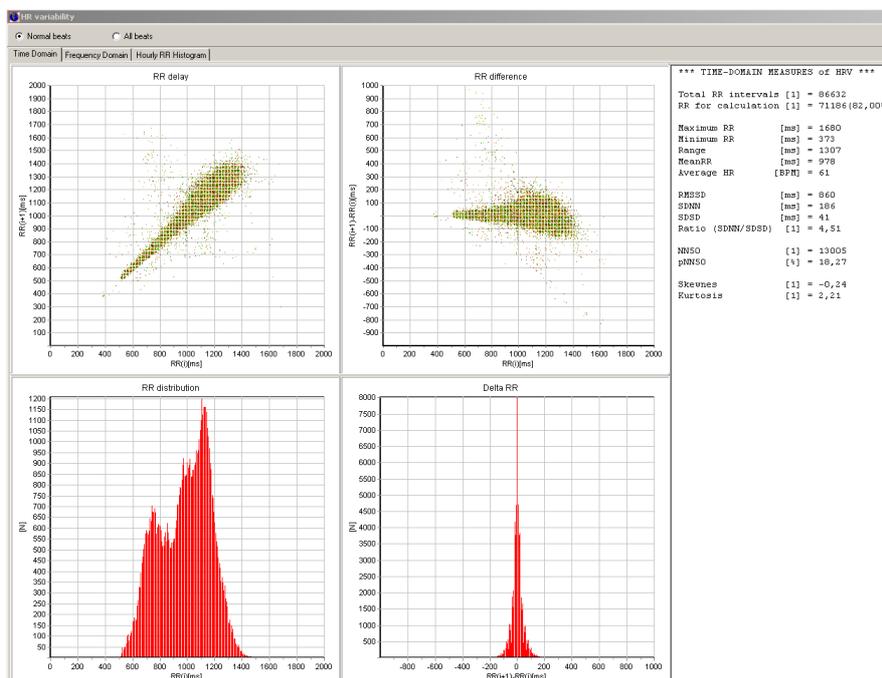
- By holding the left mouse key in the trend window and moving **up and down, the scale can be changed.**
- By holding the right mouse key in the trend window and moving the mouse, a new time window is defined and the trend window is zoomed into this new defined window. A second time bar appears (see page 37) and the signal is resized to this new window.
- By a doubleclick with the left mouse key into the trend window, the event window appears. With a second doubleclick the previous view is restored.

HRV – Heart Rate Variability

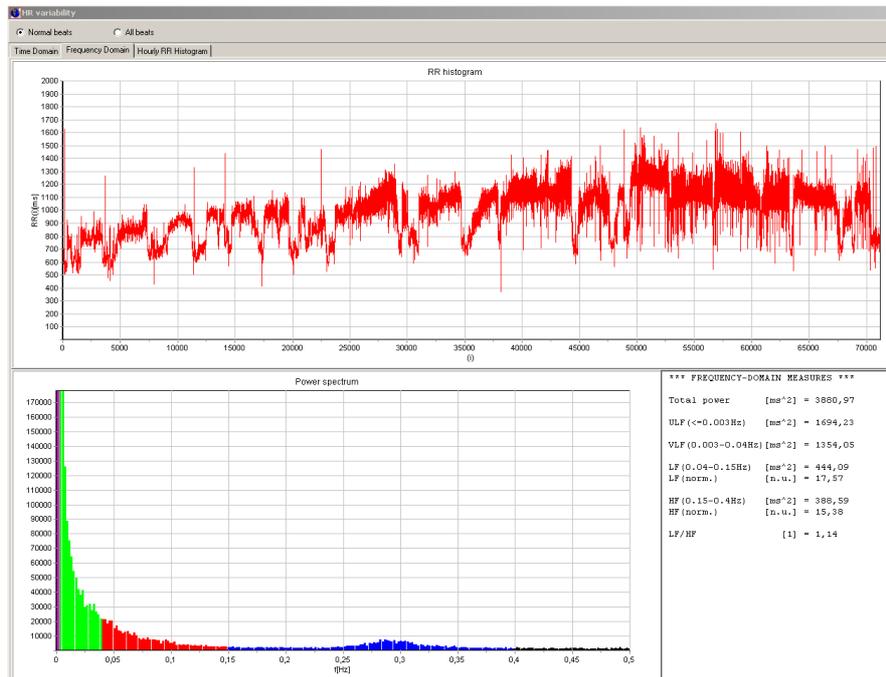


After pressing the HRV button a new menu appear which presents the results of the heart rate variability, and its available in

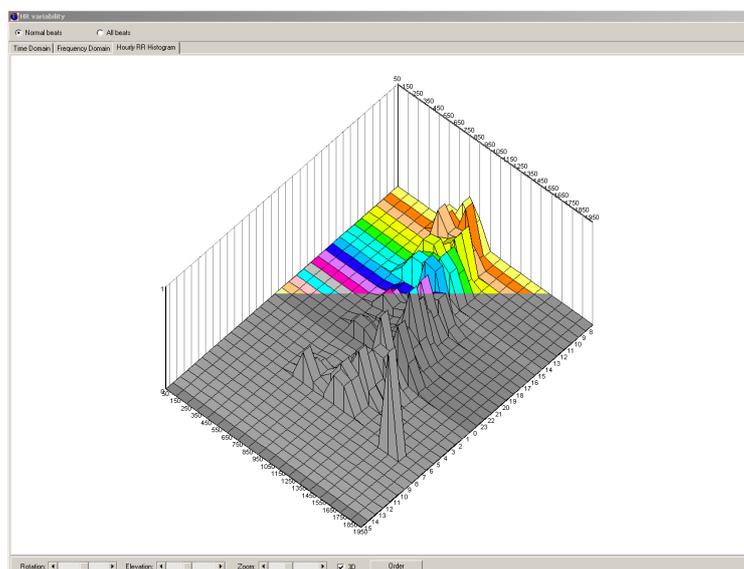
Time domain



Frequency domain



Hourly RR Histogram



For calculation you can choose only all normal beats or all beats. The hourly histogram allows you to choose between 2D and 3D presentation and you can change the time order.

The results can be printed in your report by activating the HRV option in the report generator.

Verbal Interpretation



During every analysis a verbal interpretation is automatically generated. As far as the reanalysis was made, also all changes are included in this interpretation.

The interpretation contains a summary description, information about heart rate, main events and a hourly table of the main events.

Patient was monitored for a total of 31:25:02 hours.
 The total time analyzed was 22:48:27 hours.
 Start time was 19:25:36 hours. There were a total of 86634 beats, (4.90%) were Ventricular beats, (0.06%) were Supraventricular beats.

The Mean Heart Rate was 64 .
 The Maximum Heart Rate was 114 at 19:27:15.
 The Minimum Heart Rate was 45 at 11:36:56.

	TOTAL	MIN	MAX	TIME		TIME
				FROM	TO	OF EVENT
MAIN RHYTHM EVENTS:						
MIN Bradycardia [bpm]		41		11:25:36	12:25:36	11:36:56
Longest Bradycardia				11:43:56	11:46:31	
MAX Tachycardia [bpm]			157	07:25:36	08:25:36	07:49:52
Longest Tachycardia				19:27:42	19:27:52	
SUPRAVENTRICULAR EVENTS:						
Isolated SVES	47		5	10:25:36	11:25:36	
VENTRICULAR EVENTS:						
Isolated VES	4341		943	21:25:36	22:25:36	
Couple VES	4		2	19:25:36	20:25:36	
Bigeminia VES	40		26	19:25:36	20:25:36	
Trigeminia VES	240		95	21:25:36	22:25:36	

Above you can see the first part of the generated report. You can edit and change the entrees.

EVENTS SUMMARY REPORT

Time	HEART RATE			PAUSE Number	SUPRAVENTRICULAR					VENTRICULAR				
	Min	Mean	Max		1	2	3+	Total	AF/AFL	1	2	3+	Total	
19:25	72	89	114	-	1	-	-	1	-	-	467	2	-	471
20:25	68	83	106	-	-	-	-	-	-	-	394	-	-	394
21:25	64	83	94	-	1	-	-	1	-	-	943	1	-	945
22:25	63	75	96	-	1	-	-	1	-	-	425	-	-	425
23:25	60	77	97	-	1	-	-	1	-	-	529	-	-	529
00:25	58	70	96	-	3	-	-	3	-	-	230	-	-	230
01:25	58	70	92	-	2	-	-	2	-	-	355	-	-	355
02:25	58	76	102	-	3	-	-	3	-	-	336	-	-	336
03:25	56	61	83	-	-	-	-	-	-	-	45	-	-	45
04:25	51	61	87	-	2	-	-	2	-	-	74	-	-	74
05:25	53	63	88	-	1	-	-	1	-	-	178	-	-	178
06:25	52	64	88	-	1	-	-	1	-	-	164	-	-	164
07:25	51	56	80	-	1	-	-	1	1	-	37	-	-	37
08:25	49	53	65	-	-	-	-	-	-	-	7	-	-	7
09:25	48	57	88	-	-	-	-	-	-	-	22	-	-	22
10:25	45	60	84	-	5	-	-	5	-	-	18	-	-	18
11:25	45	48	63	-	5	-	-	5	-	-	13	-	-	13
12:25	48	53	64	-	3	-	-	3	-	-	19	-	-	19
13:25	47	52	78	-	2	-	-	2	-	-	20	1	-	22
14:25	48	55	74	-	4	-	-	4	-	-	11	-	-	11
15:25	51	56	88	-	5	-	-	5	-	-	33	-	-	33
16:25	52	61	87	-	4	-	-	4	-	-	16	-	-	16
17:25	52	63	85	-	2	-	-	2	-	-	5	-	-	5
18:25	-	-	-	-	-	-	-	-	-	-	-	-	-	-

SUMMARY:

You can also edit the hourly table and at the end there is free space to include your result.

If you mark the verbal interpretation in the report generator, this text will be printed in your report.

Preferences

The preferences are used for analyze preselection and system preselection. All preselections are indirectly affecting the analysis of recording. It is possible to re-analyze a record data set.

Diagnostic

Following reference settings are possible:

- **Analysis**
Chose the channel the re-analyze is referring to.
- **Supraventrikulary tachycardy**
HR minimum: 80 – 120 [/min]
HR maximum: 200 – 350 [/min]
QRS sequences: 3 – 6 [Cycles]
- **Ventrikulary tachykardy**
HR minimum: 80 – 120 [/min]
HR maximum: 200 – 350 [/min]
QRS sequences: 3 – 6 [Cycles]

- **Supraventrikulär bradikardie**
 - HR minimum: 15 – 40 [/min]
 - HR maximum: 50 – 65 [/min]
 - QRS sequences: 3 – 6 [Cycles]
- **Others**
 - QRS similarity: 80 – 90 [%]
 - ST point to J point +: 20 – 80 [ms]
 - Too early supraventriculare event: 15 – 50 [ms]
 - Too early ventriculare event: 15 – 50 [ms]
 - Break longer than : 2 – 10 [s]
 - Break after ventrikulär extrasystol longer than: 2 – 10 [s]
 - Break after supraventrikulär Extrasystol longer than: 2 – 10 [s]

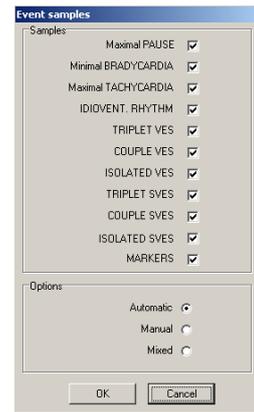
Save as standard – Save all reference settings as new standard settings for every new analysis.

Load standard – This function is used to reset the reference settings to the last saved standard without exit the Program.

Report

The register "Report" is used to preselect the contents of the printed report.

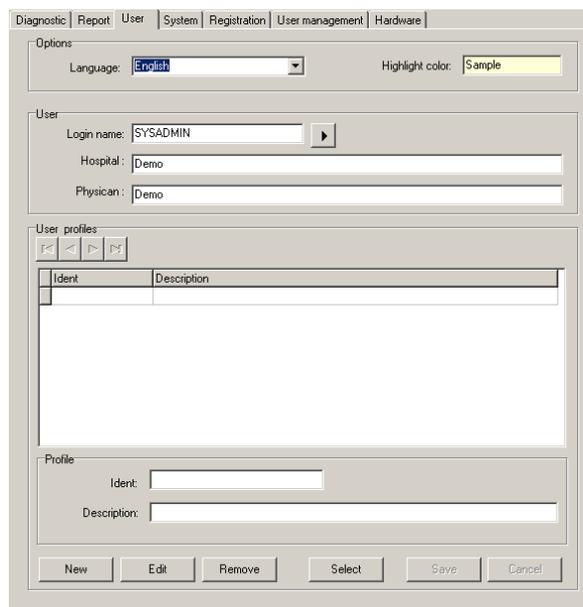
The button after event samples opens a menu to choose the events you like to print out. Additionally you can define, if the events are fixed by the system, your yourself or manually.



The button after HRV allows you to choose the print out options from the Heart Rate Variability (HRV). Choose what you like to have printed.



User



The register "User" is used to select language and insert user data.

System

Diagnostic | Report | User | System | Registration | User management | Hardware

Path and address

Working directory: C:\CardioExplorer2004\database\Archive

Archive directory: H:\DBarchive

COM device type: USB <-> RS232 COM port: COM9

Maintenance

Automatic database backup is done:

Daily First - once a day after first successful program shutdown.

Daily Last - each time after last successful program shutdown.

Weekly - once per week after first successful shutdown.

Monthly - once per month after first successful shutdown.

"Restore" function restores database tables from specified backup.

"Refresh" function reloads database from working files.

WARNINGS:

1. Only database tables are backed up -- ECG data are not included. Use export function to backup ECG data.
2. Missing ECG data could be restored using Import function.

The register "System" is used to preselect the path you are working and the filesystem you are using.

The Com device type and Com port is not used in this actual version.

Maintenance allows you to restore your database in case of trouble. Please press Restore and choose a database which you like to restore.

Registration

Diagnostic | Report | User | System | Registration | User management | Hardware

User information

Speech:

Name: Hartmut Zip code: 70188

Surname: Richter Town: Stuttgart

Title: Dipl.-Ing. (FH) State: Deutschland

Clinic: SR-Medizinelektronik Phone: +49 711 9144650

Department: Fax: +49 711 9144651

Street: Hausmannstrasse 66 E-mail: info@sr-med.de

Optional features

Basic functions:

Analysis:

Extended analysis:

Network:

Computer information

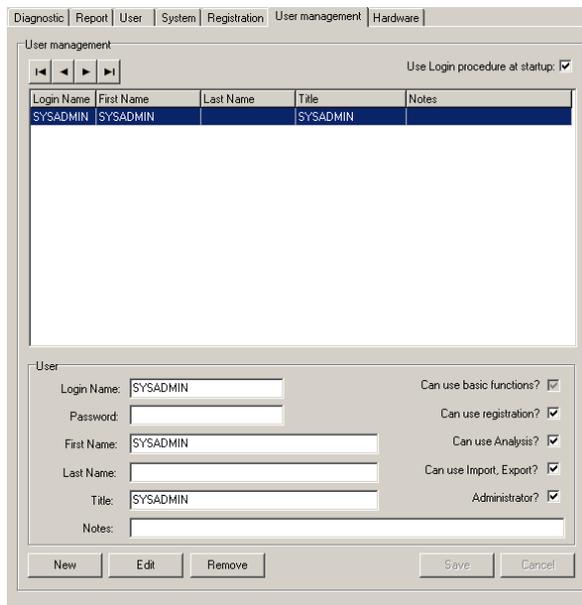
Serial number: 483763942

Registration key

Key:

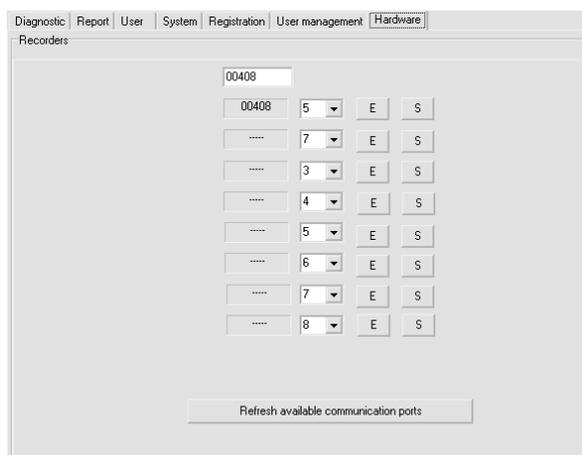
The register "Registration" is used to insert all relevant data for software registration. Only authorized specialist dealer are able to insert data in this register.

User Management



The user management sheet allows you to admistrare all included users. With the option “Use Login procedure at startup” you can diosable the login procedure.

Hardware



The Hardware sheet allows to configure the wireless interface of the recorder. After BT-pairing each recorder will have a virtual outgoing com port for communication. For defining the recorders press “E” for editing an include the serial number of the recorder and the outgoing virtual com port number, and press “S” to save this entree. Do these steps for each recorder.

6. Key functionality

General

-  <STRG> + Open start page
-  <STRG> +<d> Open data base
-  <STRG> + <a> Open analysis
-  <STRG> + <e> Open preferences

Data base

Data mask

-  <n> Start new recording or insert new patient
-  <Clr> Delete marked record data set
-  <e> Edit marked record data set
-  <s> Search function
-  <TAB> Cursor moves to next field
-  <Enter> Cursor moves to next field
-  <Shift><TAB> Cursor moves to previous field

Data overview

-  <TAB> Switch between patient listing and record listing

Analysis

Event window

-  <spacebar> Jumps to the next event of selected row

7. Declaration of Conformity

SR-Medizinelektronik, Haussmannstrasse 66, 70188 Stuttgart,

declare on our own responsibility, that the medical device

Holter System CARDIOSCOUT MULTI ECG

Holter System CARDIOSCOUT

SRA+ Rekorder

SRA Rekorder

Bodykom

ECGLink

meets all applicable requirements of Directive 93/42/EEC.

This statement applies to all products that are produced by 14.03.2020

Notified Body:

mdc, medical device certification GmbH, Kriegerstrasse 6, D-70191 Stuttgart

Conformity assessment procedures:

Directive 93/42/EWG – appendix VI

Stuttgart, 04.04.2015



Hartmut Richter (medical officer)

8. Customer questionnaire

We like to know your opinion

Please be so kind and use this questionnaire in case of problems, questions or incitation to our hard- and software system.

Your name: _____ Your address: _____

Fon: _____

Product: _____

I have the following	Problem	Question	Incitation
	Request	_____	

Please call me back

Please arrange a date

Please confirm the reception of this message

Customer sign

Please fax to: SR-Medizinelektronik – fax number +49 711 9144651