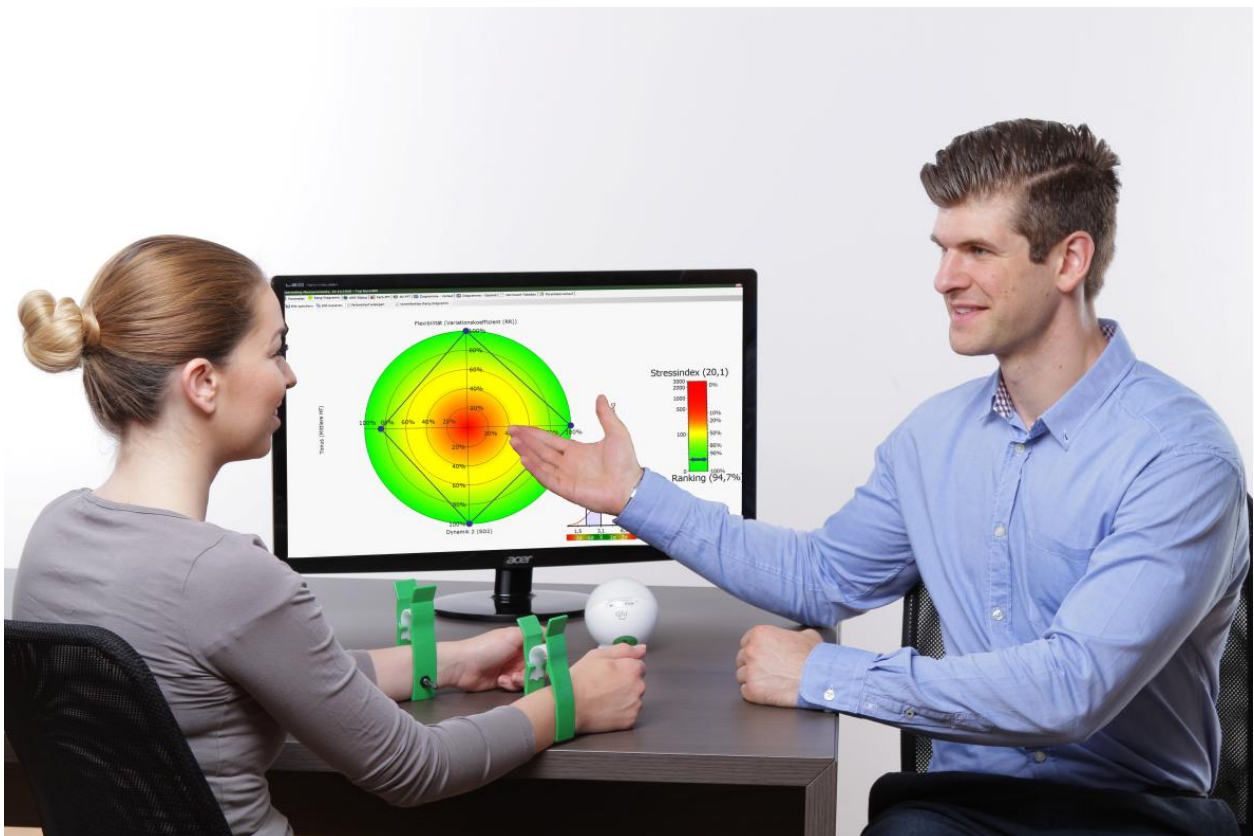


Documentation

for

HRV-Scanner



BioSign
SCIENCE FOR A BETTER LIFE

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Content

Foreword	7
Online training / support via TeamViewer	7
Questions about interpretation	7
Status of the documentation	7
Newsletters.....	7
Information for patients/clients	7
Our HRV concept	7
General	8
Setup of the HRV-Scanner software (HRV-Scanner and HRV-Scanner lite)	8
Uninstall the software.....	8
Licensing the software.....	8
Update license.....	8
Connecting the hardware	8
Start software	8
Append new examiner	8
Append new subject.....	9
The main window.....	9
Status display in the main window	9
Possible system configurations.....	9
Network mode.....	9
GDT Connection.....	9
Language selection	9
Your logo or information in the reports	9
Other important functions.....	10
Data backup.....	10
Import/Export	10
FAQ - common problems and questions	10
I made a measurement accidentally for the wrong subject	10
I forgot my access password	10
When I start the HRV-Scanner software, I am asked to enter a license code	10
I connected the hardware to the PC, but the status is "USB offline"	10
My HRV-Scanner hardware no longer shows ECG	10
Signal acquisition with the HRV-Scanner hardware during the measurement...	11
Notes on improving data quality during analysis	15
Step 1: Visual control of heart rate curve and biosignal	15
Step 2: Optimal automatic determination of the heartbeat in the biosignal.....	16
Step 3: Manual editing in biosignal.....	17
Step 4: Graphic filtering	21
Step 5: Adjust plausibility check and heart rate filters	23
Limits of HRV determination	25
Example 1: many irregular heart beats (marked in orange)	25
Example 2: Atrial fibrillation	26
Basis HRV measurements	27
The Short-Term HRV	27
Target parameter in the rank diagram of the Short-Term HRV measurement ...	30

Flexibility (Coefficient of Variation RR)	30
Tone (mean HR)	31
Dynamics 1 (SD1)	31
Dynamics 2 (SD2)	31
SD2/SD1 ratio	32
Stress index	32
Respiration and HRV	33
Influence of breathing on the results of the short-term HRV	33
Distinguishing sympathetic - parasympathetic in the short-term HRV	34
Conclusion	35
Methods for measuring breathing	35
EDR - ECG Derived Respiration (HRV-Scanner standard and HRV-Scanner lite).....	35
Mechanical determination of respiration - breathing belt (HRV-Scanner plus)	36
The Deep Breathing Test	38
Target parameter in the rank diagram of the Short-Term HRV measurement ...	41
Flexibility (E-I)	41
Tone	42
Dynamics.....	42
Why two measurements as a basis HRV	43
What has a negative impact on HRV	44
Anticholinergic drugs.....	44
Drugs with anticholinergic action	44
Further diagrams in the analysis.....	45
Poincaré Plot	45
Histogram.....	46
Spectral analysis	47
Color-FFT.....	47
ANS status.....	49
Progression of parameters	50
List of parameters.....	51
Calculate heart rate from []	51
Sampling rate [Hz]	51
Duration [hh:mm:ss]	51
Number of heartbeats [n]	51
Artefact ratio [%]	51
Well-being [%].....	51
DBT quality [%]	51
Test quality [%]	51
Biofeedback quality [%]	51
Subject age [years]	51
Subject height [cm]	51
Subject weight [kg] (initial)	51
Subject sex.....	51
Examiner	51
Mean HR [1/min.]	52
Standard deviation (St.Dev.) [ms]	52

Coefficient of variation (HR) [%].....	52
Mean RR interval [ms].....	52
SDNN [ms]	52
PNN50 [%]	52
PNN20 [%]	52
Coefficient of variation (RR)	53
RMSSD [ms]	53
SD1 [ms].....	53
SD2 [ms].....	53
SD2/SD1 quotient.....	53
Normalized SD2/SD1 quotient [σ].....	54
Stress index [Pts.]	56
HF-Band [Hz]	57
LF-Band [Hz].....	57
VLF-Band [Hz].....	57
Power HF-band [ms^2].....	57
Power LF-band [ms^2]	57
Power VLF-band [ms^2]	57
Power total [ms^2]	57
rel. Power HF-band [%].....	57
rel. Power LF-band [%]	57
rel. Power VLF-band [%]	57
LF/HF ratio.....	57
Rhythmisation degree []	57
E-I [1/min.]	58
E/I []	58
MCR []	58
Ewing 30:15 value [].....	58
Biological HRV age [years].....	58
Valsalva-Ratio	59
Alpha 1 []	59
Respiration parameters	60
Impact breathing [%]	60
Respiratory rate [1min.]	60
Respiration stress[].....	60
Breathing variability []	60
Pulse wave latency [ms]	60
HRV biofeedback	61
HRV biofeedback	61
Online spectral analysis (Real time FFT).....	62
Rhythmisation	62
Fundamentals of HRV Biofeedback	63
From chaos to order.....	63
Breathing is the key to coherence	63
As you learn, breathing and heartbeat are rhythmic	64
How to improve coherence through biofeedback	64

What to do if coherence is always low?	64
What does the balloon mean in the centre of the screen?	65
How often and how long should you practice HRV Biofeedback?	65
Important settings in HRV Biofeedback	66
Breathing rhythm	66
Exercise duration	66
Rhythmization degree target value (difficulty level of the exercise)	66
Qiu and HRV-Scanner	67
The Qiu	67
The Qiu-Modul in the HRV-Scanner-Software.....	67
Qiu-Configurator.....	67
Connecting the Qiu to the PC.....	67
Assigning a Qiu to a subject	67
Configuration of the breathing display on the Qiu	68
Determine the exercise difficulty	68
Set the exercise duration	68
Configuring the brightness of the biofeedback.....	68
Additional functions.....	68
Set the date / time of the Qiu	68
Clear the Qiu's measurement memory	68
Qiu Signal Check.....	68
Ear clip as an alternative.....	69
Qiu measurements.....	69
Defining the exercise plan by day of the week and time of day	69
Management of Qiu measurements	69
Rework the measurement	69
Overview of the exercise success with statistical evaluation.....	70
Statistical evaluation:	70
Filter settings	70
Overview of Exercise Compliance, Compliance Index	71
HRV-Monitoring with the Qiu	72
Instruction	72
How do you turn the Qiu on / off?	72
How can I leave the setting mode if it was accidentally activated when switching on?	72
Which holding position is suitable?	72
Which sensor position is suitable?	72
How do I recognize an inappropriate sensor position?	72
The optical biofeedback stays permanently on red or green, no matter what I do?	72
What does the wandering blue LED light at the equator of the Qiu mean?	73
Why does the Qiu light up brightly when it turns on?	73
After the bright light when switching on the Qiu flashes recently red once again, why?	73
After the light comes on, the Qiu flashes red three times and then turns off, why?	73
Does the time and date in the Qiu have to be reset after changing the battery?	73
How can the subject change the batteries?.....	73
Additional HRV tests	74
HRV supine/standing.....	74
Long term measurements	75
Long-term Analysis - Step 1 - Diagrams	75
Long-term Analysis - Step 1 - View	76
Long-term Analysis - Step 1 - Filter	78
Long-term Analysis - Step 1 - Tables.....	80
Long-term Analysis - Step 1 - Protocol	80
Long-term Analysis - Step 2.....	81

Long-term Analysis - Step 2 - HRV Progress.....	82
Extended 24h analysis	83
Detailed assessment of measurement quality	83
Abnormalities in the HRV	86
Spiderweb charts with normative percentiles.....	87
Assessment of nocturnal recovery.....	89
Specific performance indexes for the sympathetic and parasympathetic nervous system	90
„Functional HRV Age“ and „Premature Aging (PMA)“	91
Functional HRV age as a risk	94
Sleep	95
Working with templates in the HRV-Scanner	98
Creating Templates.....	98
Analysis with Templates	99
Summary Report	101
Creating a Summary Reports	101
Result	103
Definition of the scoring algorithm of a summary report	104
Step 1: Selection of the individual parameters.....	104
Step 2: Defining the evaluation criteria for each parameter (defining scores)	104
Step 3: Evaluation criteria for a single test.....	105
Step 4: Evaluation of the complete functional analysis.....	105
Import Options	106
ASCII	106
ASCII biosignals	106
EDF - European Data Format.....	106
eMotion HRV	106
Polar	106
Suunto	106
SRM long term measurement	106
Possibilities of ECG derivation.....	107
Derivation of a 1-channel ECG with clamp electrodes	107
Derivation of a 1-channel ECG with adhesive electrodes	108
Derivation of a 3-channel ECG (only HRV scanner hardware plus)	108
Technical Manual HRV-Scanner Hardware plus	109
Prepare the Breathing Sensor.....	109
The Valsalva pressure sensor set	111
Technical Manual	112
PC Hardware PC Requirements	112
Maintenance and Servicing.....	112
Copyright.....	112
Liability	112
Warranty	112
Technical details	112
Appendix - Literature	113
Literature SD2/SD1 ratio	113

Foreword

Thank you for your interest in our HRV-Scanner system. BioSign has been active in the area of heart rate variability (HRV) and the analysis of the vegetative nervous system for over 20 years. The HRV-Scanner software as a major part of our HRV concept reflects our know-how gained over the years and is therefore quite extensive in some areas. We would be happy to answer any questions you may have and we would be pleased to assist you with our product.

Online training / support via TeamViewer

When purchasing a HRV-Scanner, or when using our free demos, we offer you online support or training via TeamViewer®. All you need is a PC with internet access on which the HRV-Scanner software is installed and a telephone. If you are interested, make an appointment with us. In addition, we offer seminars and full-day trainings. You can find more information on our homepage at **www.biosign.de**

Questions about interpretation

You have questions about the technical quality of your HRV measurement, or how to interpret the results? Please contact our free support by e-mail (info@biosign.de). For a fast and competent support, we have installed an export possibility of measurements in the HRV-Scanner. So we can look at the measurements and give you tips and interpretation aids.

Status of the documentation

This documentation represents the status of the HRV-Scanner software when printing the copy in your hands. However, since we also do some scientific research and always make an effort to integrate the current state of science into our products, there are always changes and innovations in the software. All of our new features are fully accessible via our online software update system. Changes in the software also lead to a need to update this documentation from time to time. Therefore you will always find a current version of this documentation as a PDF file together with the updates in your software under "Help".

Newsletters

Would you like to be kept up-to-date? We would be glad to send you our newsletter. This usually happens automatically when you buy one of our systems. You will receive our newsletter without obligation. You can unsubscribe at any time. The newsletter provides information about new software features or other important innovations for HRV-Scanner users.

Information for patients/clients

Do you need information material for your patients/clients? We offer flyers, posters, info brochures, info maps and much more. You can find more information in our online shop at **www.biosign.de**

Our HRV concept


In addition to the HRV-Scanner, we also offer HRV biofeedback devices for your patients/clients. This enables us to provide you an HRV monitoring concept for objective monitoring your therapy or intervention. The measurement data are accessible in the terminals or via an Internet cloud and trends can be calculated.

Please note that not all features listed in this documentation are available in the HRV-Scanner lite software.

General

Setup of the HRV-Scanner software (HRV-Scanner and HRV-Scanner **lite**)

Please download the current setup from our homepage (**www.biosign**). The setup can be found under: **HRV-Scanner -> Downloads ->**

 <p>aktuelles Setup HRV-Scanner/HRV-Scanner lite als EXE-Datei für Windows 7/8/10</p>	Run the HS_Setup.exe program. To avoid problems with Windows user administration, we recommend an installation in a directory as proposed in the setup (C: \HRVScanner)
--	---

Uninstall the software

Uninstall the HRV-Scanner software by using the Windows Control Panel.

Licensing the software

The software license is located on the blue HRV-Scanner dongle, which must be connected to USB to run the software. Alternatively, there is the option of an online license via the Internet. *Note: You can install the software on any number of PCs. The software runs where the blue HRV-Scanner dongle (license) is attached.*

Update license

The HRV-Scanner software runs without time-limits. When you buy a system, you get 365 days of update license. This allows you to benefit from all further developments of the HRV-Scanner software free of charge. The software checks, at intervals (to be defined in the system control of the HRV-Scanner software), whether new updates are available and then downloads them from the BioSign server and installs them.

An extension of the update license after expiration is possible at any time. Use the order option in the HRV-Scanner software.

Connecting the hardware

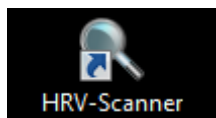
Connect the HRV-Scanner hardware to your PC using delivered the USB cable. The HRV-Scanner software should not be started. Wait for the drivers of Windows to be installed and until Windows says, that the device can be used now.

Start software

First plug your HRV-Scanner dongle into a free USB port. If you do not have a free USB port, we recommend using a USB hub (included with the HRV-Scanner). Start the HRV-Scanner software by double clicking with the mouse on the HRV-Scanner symbol. Depending on which version you have received you can either run only the HRV-Scanner **lite** software or the HRV-Scanner and the HRV-Scanner **lite** software.

HRV-Scanner software

Full version with all features



HRV-Scanner **lite** software

Starter version for Windows Tablet and PC



Tip: At the beginning, the **lite** version can make the entry much easier since the user is guided by the software through measurements.

Append new examiner

When you first start the HRV-Scanner software, you must first create a new examiner. Enter the data for the new examiner. The password is optional and should be entered if a data record is to be protected against unauthorized access. After recording a new examiner, it appears in the login window. Press "OK" to log in to the system.

Append new subject


Before a measurement can be performed, the subject data must first be entered. To do this, go to the main menu and press "Subject" and then "Append new subject". After recording a subject, you can perform the first measurement.

The main window

After logging in to the examiner, you enter the main window of the HRV-Scanner. From here you can reach all other program features.

Status display in the main window

The status display is shown in the main window at the bottom right

HRV-Scanner	Study	←	Version of the HRV-Scanner Software (Compact, Professional or Study)
Version	V 3.04.06	←	Software version
Dongle serial	1721449808	←	Serial number of your Dongle or info about online license
Update-Licence	365 remaining days	←	Remaining days for updates from the internet. Are there new updates available?
Network	Local	←	Local or network mode
Subject mode activated 			

You will also see in the status line below which examiner is logged in, whether you are in the subject or study mode, and the current percentage size of the software scaling.

Possible system configurations

Network mode

It is possible to run the HRV-Scanner software in network mode. This allows data to be stored centrally and used by several clients (examination room, meeting room, ...)

GDT Connection

A transfer of the patient data from a doctor's office software is possible via GDT.

Language selection

The HRV-Scanner software is available in several languages. Select the desired language in the system settings.

Your logo or information in the reports

You can include your logo and other information in the header of the reports

Other important functions

Data backup

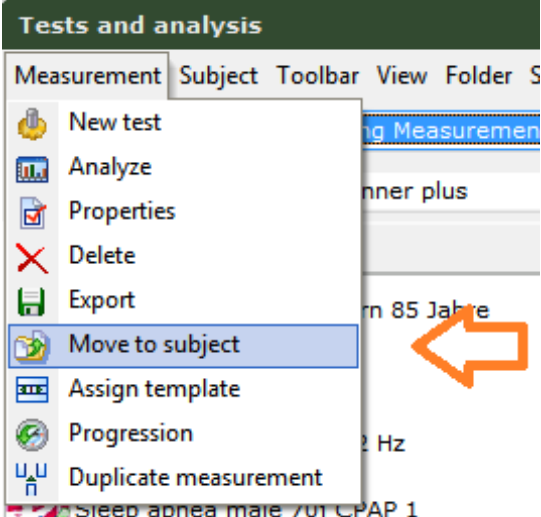
We recommend to regularly back up the data. There is a separate function in the HRV-Scanner software. Tip: we also recommend to save the entire HRV-Scanner directory, including all subdirectories, to an external data medium from time to time.

Import/Export

The HRV-Scanner software has an export/import system, which allows the export of measurements including all information on the subject. You can use this for data exchanged between several HRV-Scanner systems and also for the support. You can send measurements with anonymous test data by e-mail to us and write any questions.

FAQ - common problems and questions

I made a measurement accidentally for the wrong subject

	<p>Measurements can be moved to another subject. Use the function "Move to subject" in the title menu of the "Test and analysis" window.</p> <p>In the displayed window, select the subject to which the measurement should be moved.</p>
--	---

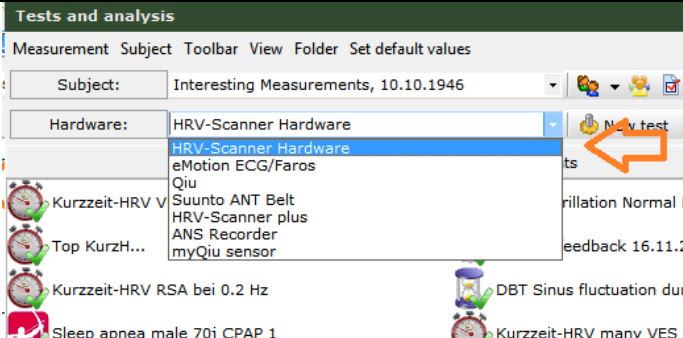
I forgot my access password

Please contact us by e-mail and send us the file "HRVScanner.mdb" from the HRV-Scanner directory by e-mail. We can read the encrypted file and give you your password.

When I start the HRV-Scanner software, I am asked to enter a license code

Is your USB dongle connected to the PC? Possibly the dongle is not recognized. This problem can often be solved by using the included USB hub.

I connected the hardware to the PC, but the status is "USB offline"

	<p>Did you select the right hardware before starting the measurement?</p>
---	---

My HRV-Scanner hardware no longer shows ECG

Do you still have a device from the first generation (battery compartment on the bottom). Then replace the batteries with new and charged batteries.

Signal acquisition with the HRV-Scanner hardware during the measurement

The HRV-Scanner software is compatible with several devices for signal acquisition. Devices are used via USB and Bluetooth. This chapter explains the acquisition of a 1-channel ECG and the pulse wave using the HRV-Scanner hardware.

***Note: We recommend that you take care for a good biosignal while measuring.
This avoids the post-processing during the analysis.***



Connect the hardware elements, as shown in the picture. If the banana plugs cannot be inserted into the brackets, please turn the top wheel upwards. Plug the USB cable into an available USB port on your PC. If no free USB port is available, please use the included USB hub.

The drivers are installed when connecting the hardware to the PC for the first time. Please wait until this process is finished!

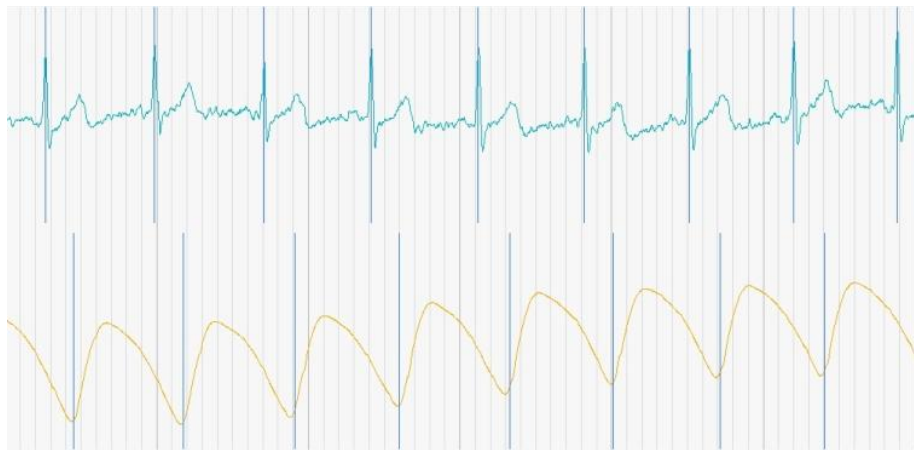


Apply the ECG clamp electrodes to the subject. In contrast to the picture above, in most cases the red cable should go on the right hand. Important is that the R-wave in the ECG points upwards. If the wave is pointing downwards, the ECG clamp electrodes should be replaced right/left. The ECG paper should be moistened with water and laid under the ECG clamp electrodes. Alternatively, electrode gel can also be used.

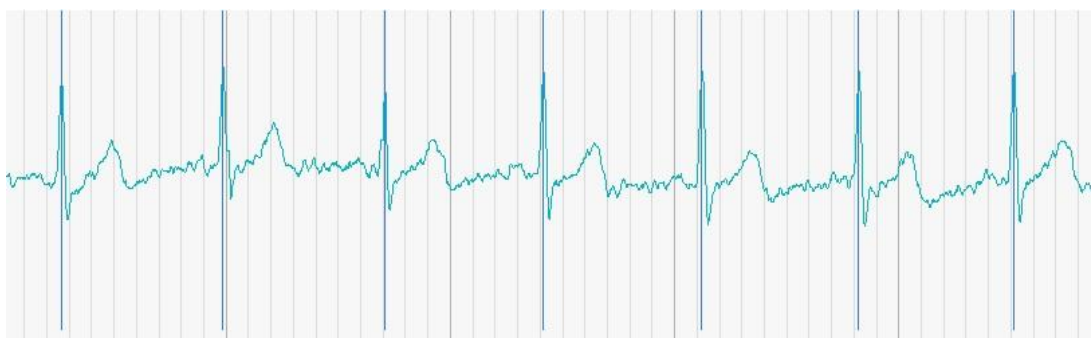
Further possibilities can be found in the chapter: **Possibilities of ECG derivation**



Place the ear clip as shown in the picture. Attach the silver holding clip of the cable at the shirt collar or neckline of the subject's clothes.



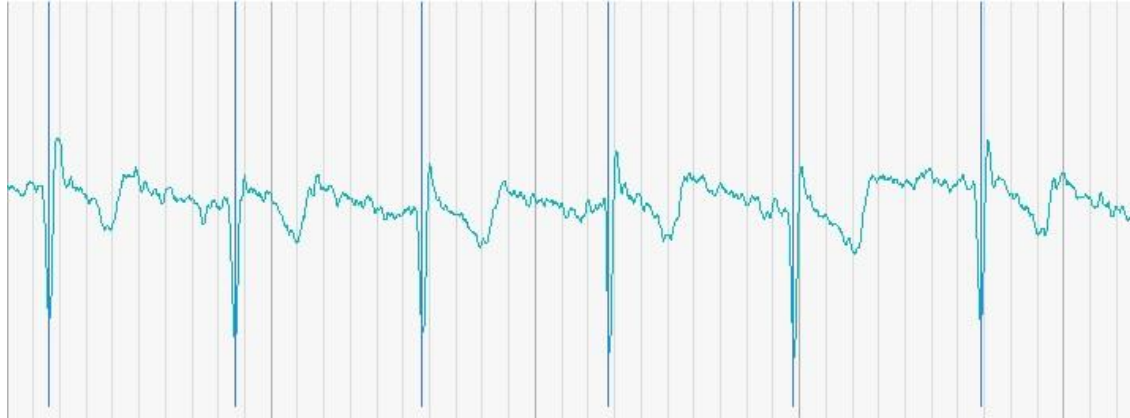
Two kinds of biosignals are basically recorded by the HRV-Scanner software. The ECG (taken off with clamps or electrodes) and the pulse wave (taken off with the ear clip). When using alternative hardware, depending on what hardware you are using, either both or only one of the two signal sources are available. E.g. the HRV-Scanner hardware records ECG and pulse wave, the Faros 180 only ECG, the Qiu and the myQiu hardware only pulse wave.



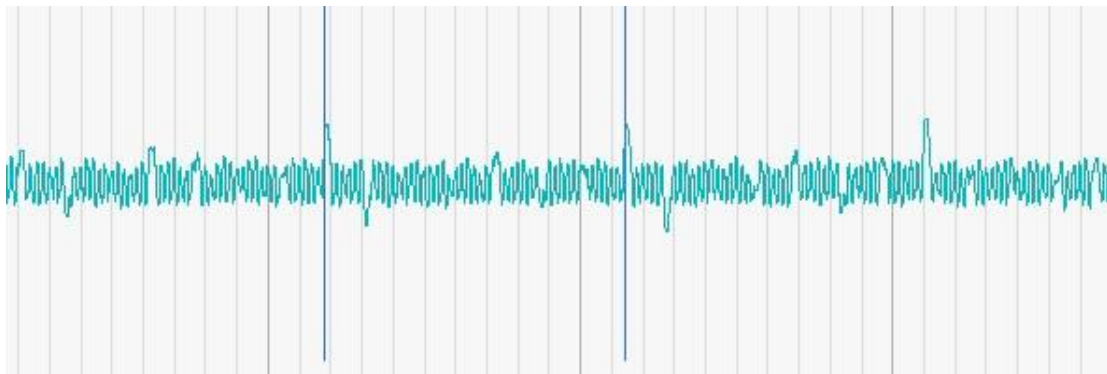
Here is an example of an optimal ECG signal. The sharp R-waves are clearly visible and directed upwards. The baseline of the ECG is slightly noisy and the R-waves are clearly distinguished in size from the rest of the signal. The vertical bar in the R-waves indicates that the software has detected and marked a heartbeat.

The shape of the ECG with its sharp R-wave makes it possible to set the time of a heartbeat very precisely. The pulse wave is a rather soft, vibrating signal. Here, setting the time of a heartbeat is more difficult and somewhat inaccurate. Furthermore, the pulse wave also is influenced by the regulation of the vessels, which may additionally increase the deviation compared to the accuracy of the ECG.

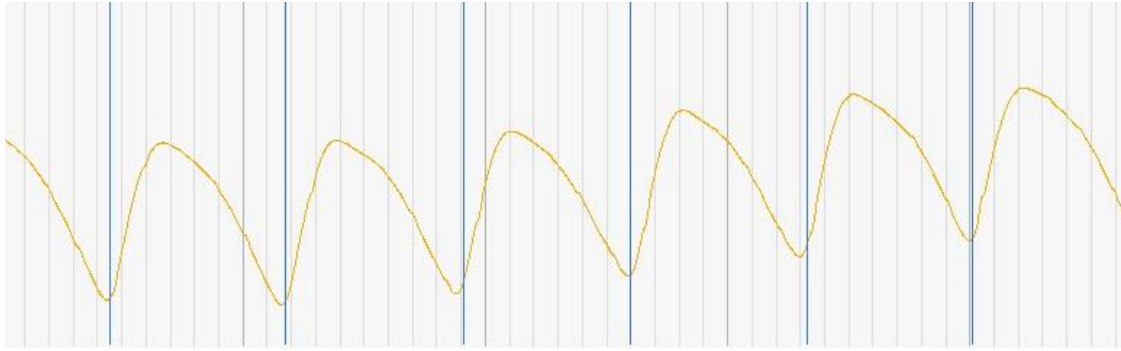
As a result, the ECG (and possibly in addition the pulse wave) should be used for HRV measurements (Deep Breathing Test, Short-Term HRV). The accuracy of the pulse wave alone is sufficient for the HRV biofeedback. Also because of the simpler application in practice one can use the pulse wave without hesitation to the HRV biofeedback.



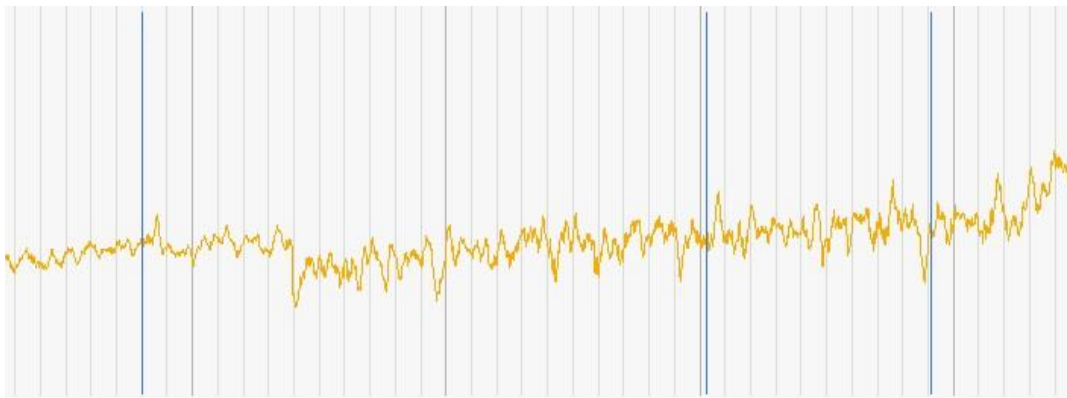
Here is an example of a non-optimal ECG signal. The high and sharp R-waves are clearly visible but directed downwards. This is called a wrong polarized ECG. This can be easily corrected by changing (left to right) the electrodes.



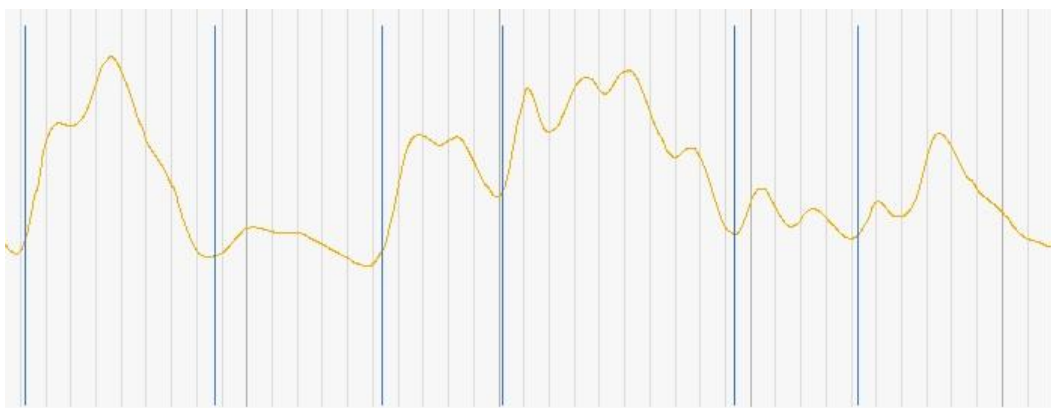
Here is an example of an unusable ECG signal. The R-waves are no longer clearly visible and their height is only slightly greater than the ground noise. One speaks here of a noisy ECG. The cause is either a source of interference (e.g., a fluorescent lamp, a defective charger on a notebook) or an insufficient electrical conductivity on the electrodes. To eliminate this, remove the source of interference (turn off the lamp, unplug the charger from the notebook) and place the moistened electrode paper under the clips.



A good pulse wave should look like this. The signal is similar to a sine wave. The zero line is clearly visible. The large vibrations correspond to the blood volume flow through the blood vessels. The blue vertical lines mark a detected heartbeat.



Here is an example of a bad pulse wave. The signal is very small and the individual volume pulses cannot be detected exactly. The ear clip should be positioned at a different location on the earlobe or to the other earlobe. It may also be helpful to rub the earlobe slightly before applying the ear clip to increase blood flow.



Here is an example of a pulse signal, which was shaken by movement of the subject. To avoid this, the subject should always keep the head calm during biofeedback/measurement. It also helps, when the cable with the silver clip is fixed at the shirt collar.

Notes on improving data quality during analysis

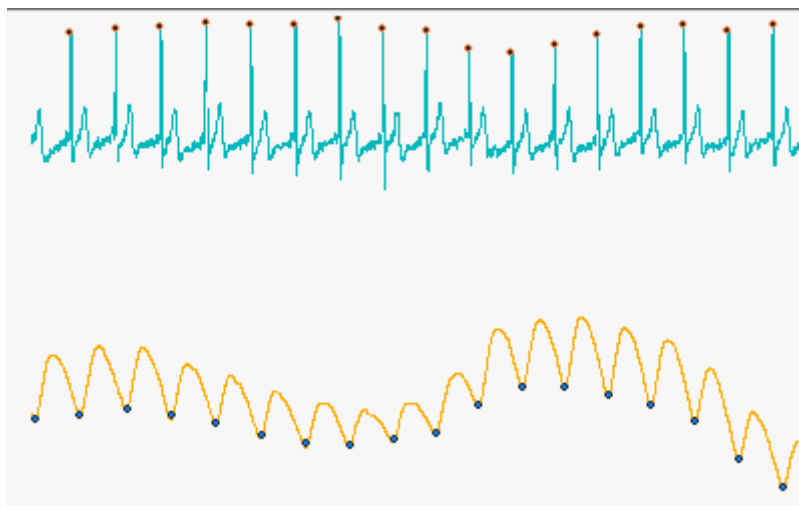
The registration of heart rate variability (HRV) provides valuable information about the state of the autonomous regulation. However, a requirement is a very high quality of the measurement, e.g. a very clean detection of the heart rate curve. There is hardly a medical method that is as sensitive to disturbances and artefacts as the HRV analysis. Even a single artefact in a 5 minute short term HRV may corrupt certain HRV parameters (e.g., RMSSD) by more than 100%.

For this reason, the accurate control of the heart rate curve and, if necessary, careful removal of all artefacts is the basis for a valid HRV evaluation. The following procedure has proved successful:

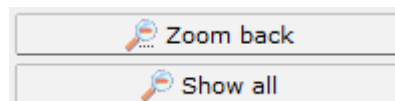
- **Step 1: Visual control of heart rate curve and biosignal**
- **Step 2: Optimal automatic determination of the heartbeat in the biosignal**
- **Step 3: Manual editing in biosignal**
- **Step 4: Graphic filtering**
- **Step 5: Adjust plausibility check and heart rate filters**

Step 1: Visual control of heart rate curve and biosignal

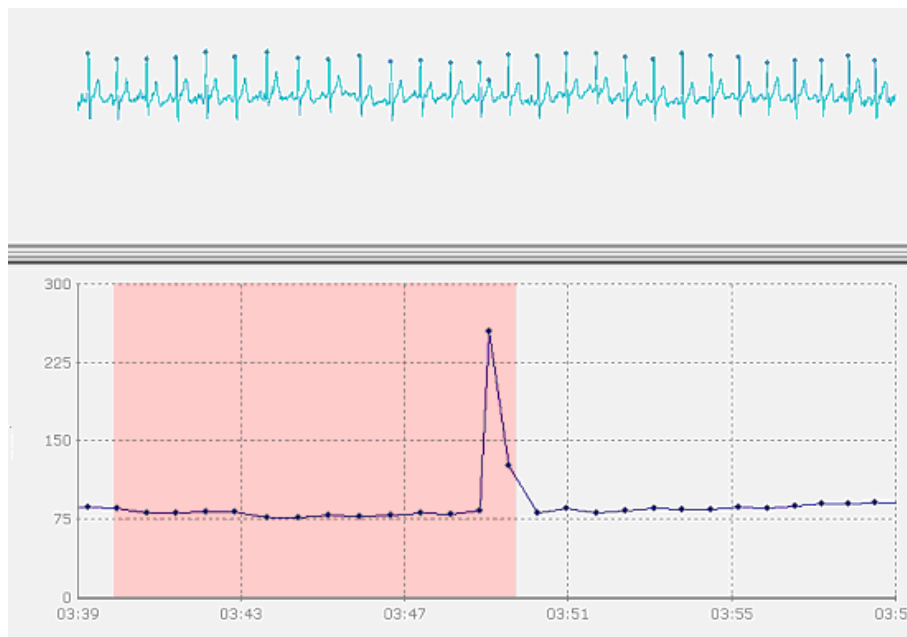
Both in the ECG and in the pulse wave signal, the heartbeat leads to characteristic signal fluctuations, which allow an accurate time determination of the heart activity. In the ECG, it is the R-wave, in the pulse wave the beginning of the steep rise



The HRV-Scanner indicates detected R-waves or detected pulse waves by a small orange (ECG) and blue (pulse wave) circle (see figure). It is recommended to scale some areas and confirm the correct position of the marks visually. You can scale by simply dragging a frame, with the left mouse button pressed, around the area of interest. The original scale can be restored by pressing the following buttons:

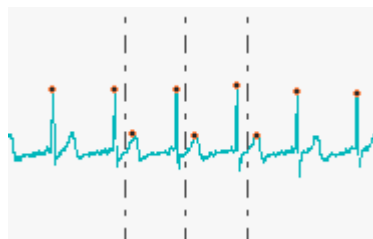


If the marks are incorrectly flagged, this leads to sudden jumps of the heart rate trace, which can be easily detected visually (see figure).

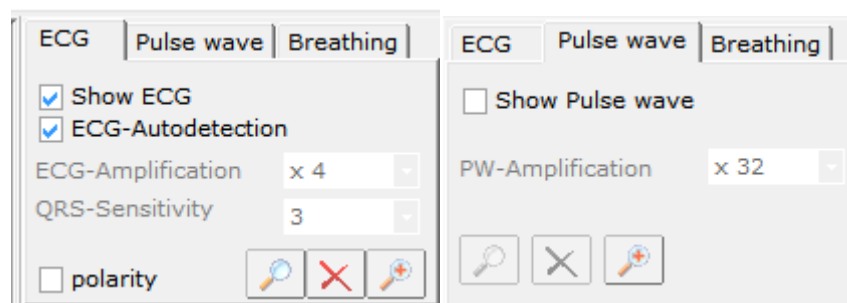


Step 2: Optimal automatic determination of the heartbeat in the biosignal

When the marks are systematically wrong or missing, re-running the automatic detection of heartbeats might fix the problem. Observe the lower figure: you will see that in addition to the correct detected R-wave, the T-waves have also been flagged.



This results in a wrong heart rate of over 200 beats per minute! Obviously, the sensitivity of automatic heartbeat detection is set too high. To change the sensitivity, you can adjust the settings for signal size and sensitivity (see picture).



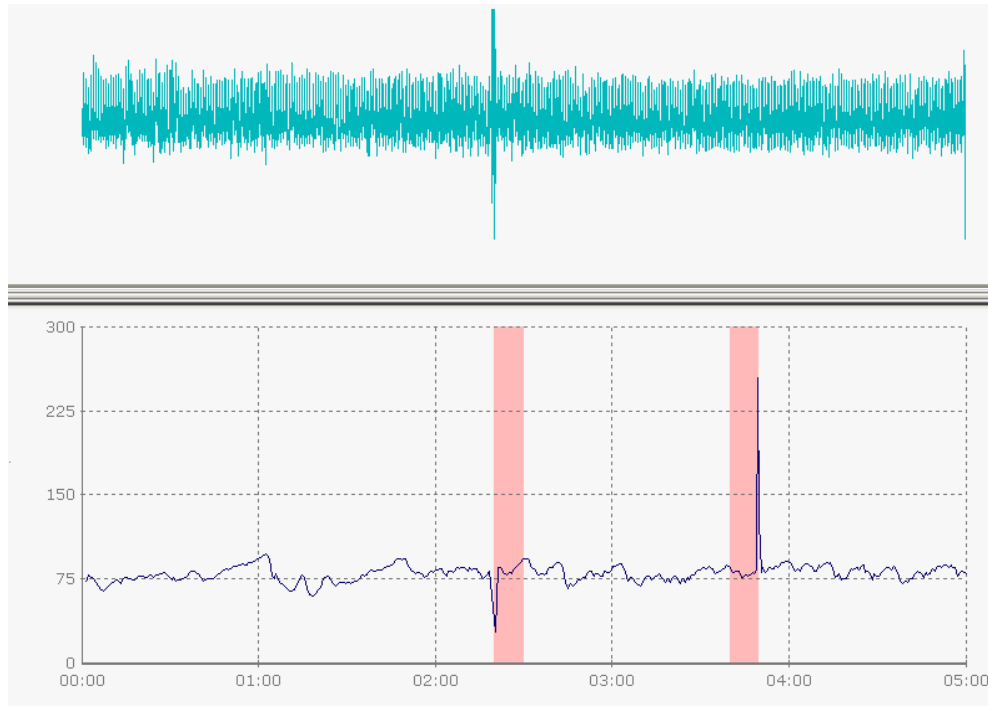
Change the settings for the biosignal you want to edit here. The ECG auto detection is activated by default. If this does not provide a satisfactory result, you should disable auto detection and manually adjust the amplification and QRS sensitivity settings.

Note: You must press the button with the magnifying glass symbol in order to run a complete re-analysis of the heartbeats with the changed settings!

Check the result visually and repeat the procedure, if necessary, until you cannot improve the quality of the data in this way. In this case, go to the next step and work out the remaining artefacts manually.

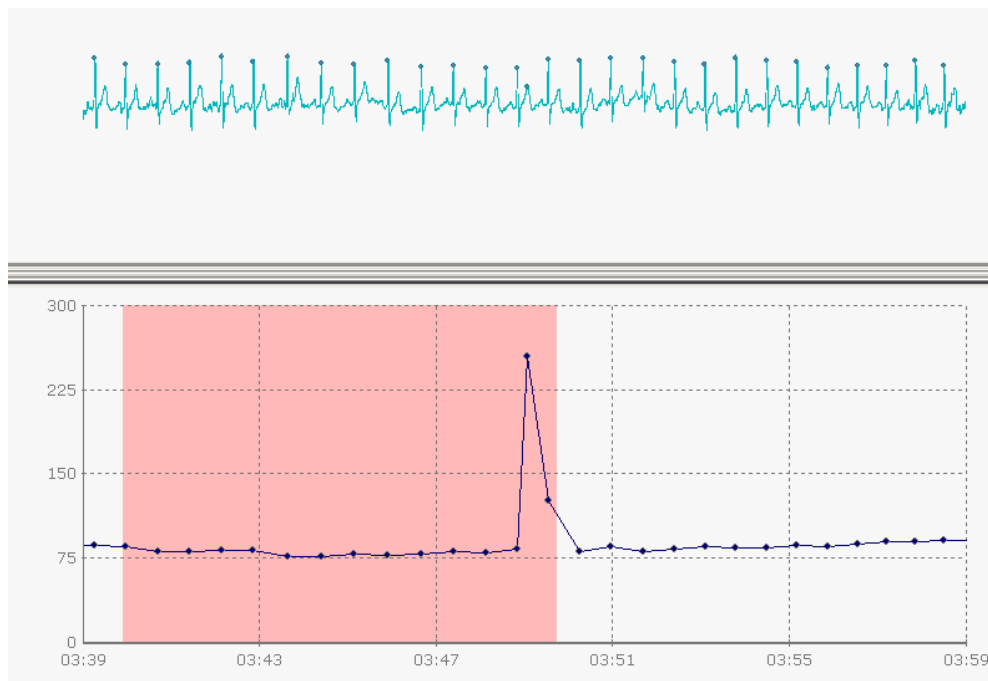
Step 3: Manual editing in biosignal

For shorter measurements (<10 minutes) and longer measurements with few artefacts, these should preferably be removed manually.

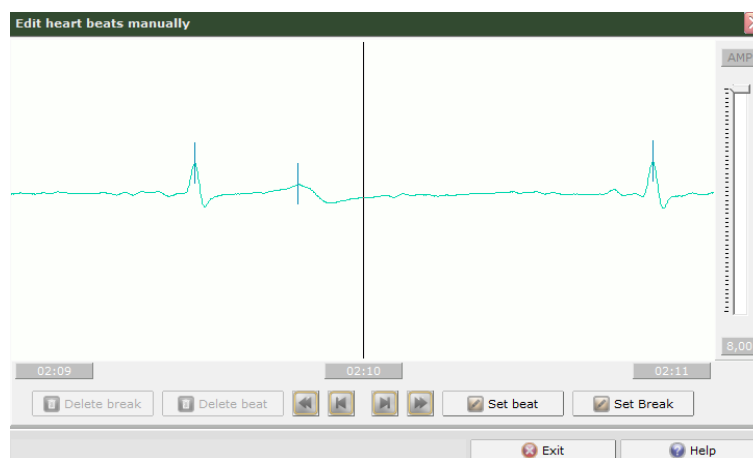


In the example shown, two artefacts were criticized by the Quality Wizard. A conspicuous deflection of the heart rate downwards, and a noticeable deflection of the heart rate upwards.

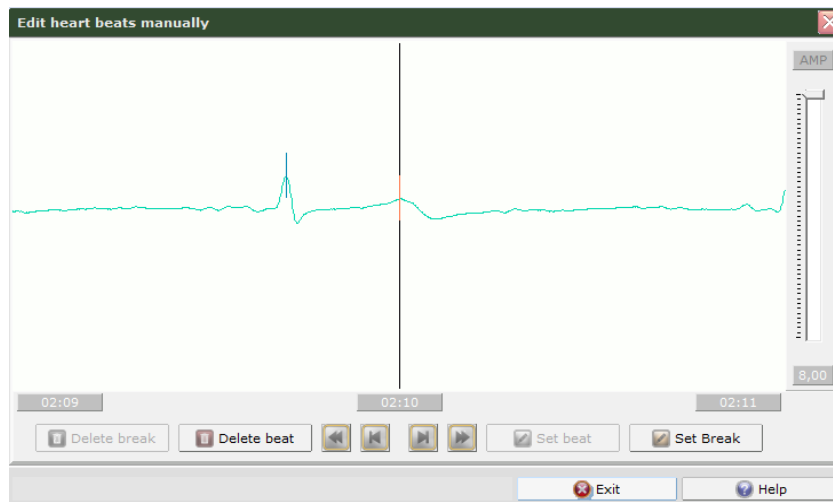
Such jumps should always be a reason to look more closely at the corresponding biosignal. Press the left mouse button and drag a frame around the jump in heart rate to scale the diagram (see figure).



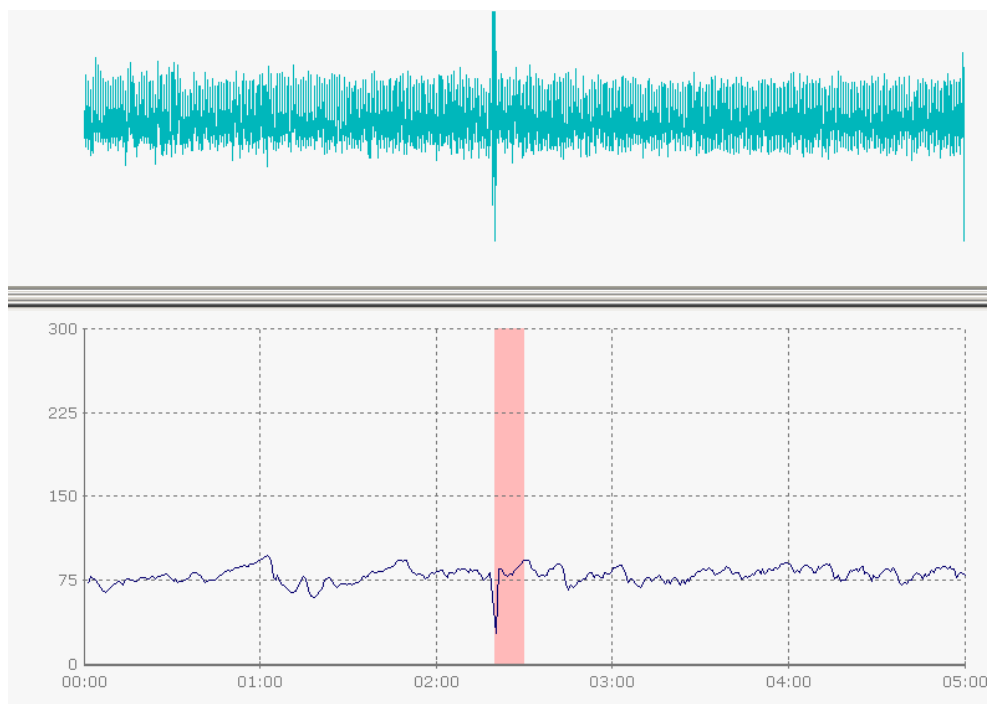
Now double-click on the point of interest . It doesn't matter whether you click in the biosignal diagram or in heart rate diagram. The double click starts the biosignal editor.



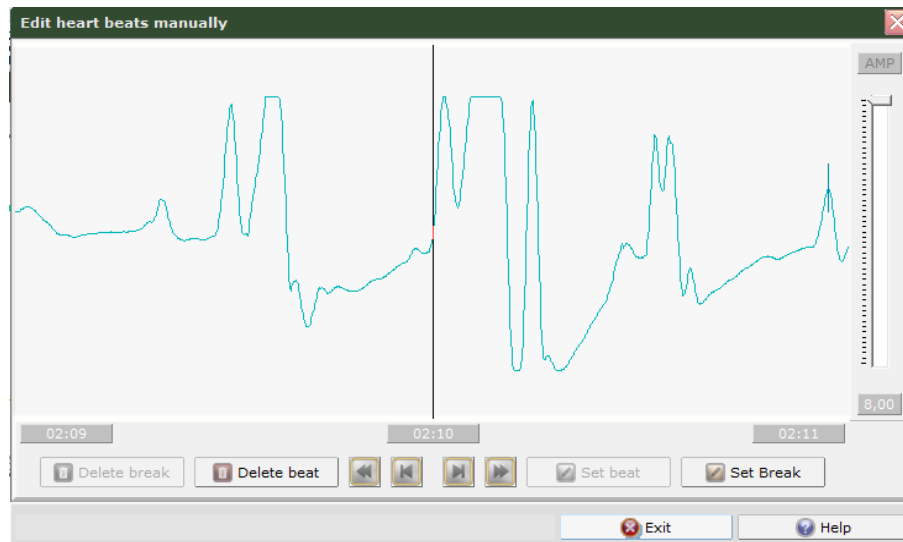
With the biosignal editor you can set and delete marks manually. Use the arrow buttons to move through the signal, until the vertical line in the middle is aligned with the point of interest. In the example above the T-wave is obviously marked as heartbeat. Here we have scrolled through the signal until we reached the incorrect mark (see figure).



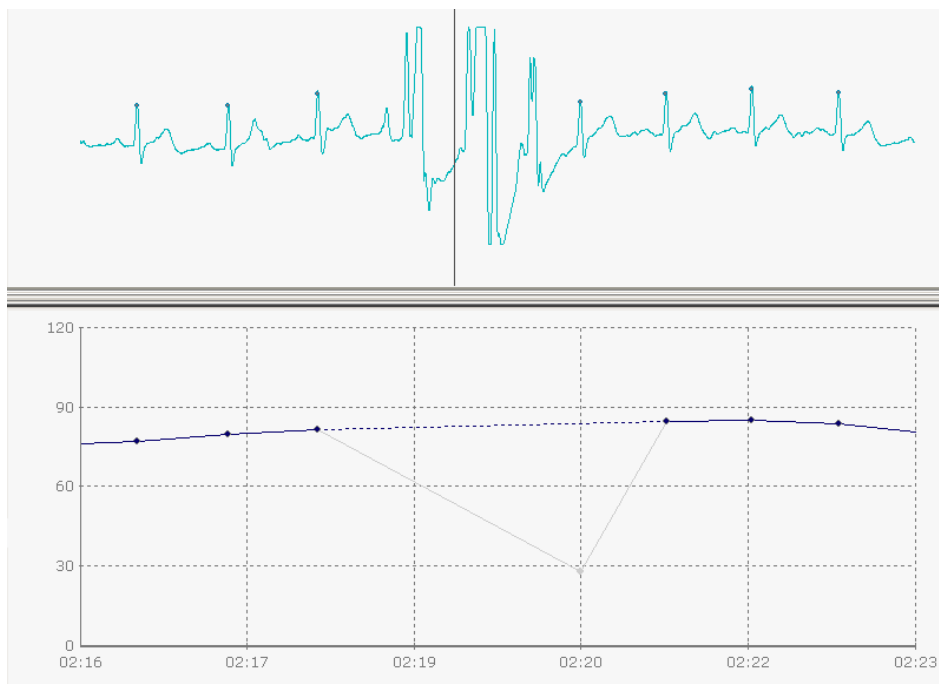
If the centre line is over a marked beat the “Delete beat” button will be enabled. Press this button to remove the mark. The artefact is now cleared.



The second artefact, with the downward deflection, can be solved in the same manner. Scale the area of interest and start the editor (see figure).

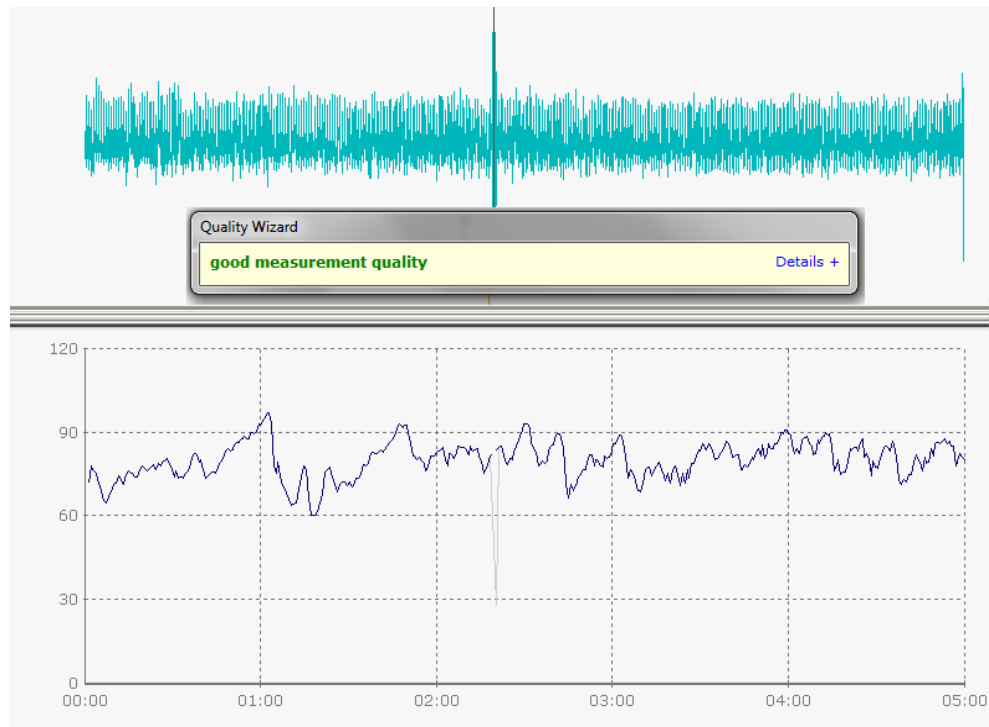


Unlike the first example, we see here a more or less confused signal without any marks. It is impossible to detect the R-waves reliably. This explains the apparent downward jump: the time interval between the last detected R-wave before the disturbance and the first detected R-wave after it is several seconds long. This gap translates into a very low heart rate (remember: the heart rate of a single pair of heartbeats is computed by the formula $60 \text{ divided by the inter-beat interval, in seconds}$). In order to remove this kind of an artefact we insert a "break" somewhere inside the signal disturbance. A "break" instructs HRV-Scanner not to calculate a heart rate for this time interval.



Now look at the diagrams. You can see the break is marked by a vertical line in the signal diagram. In the heart rate trace a dotted line indicates the break area. There is also a fine grey line, which signals how the heart rate trace would have looked without correction.

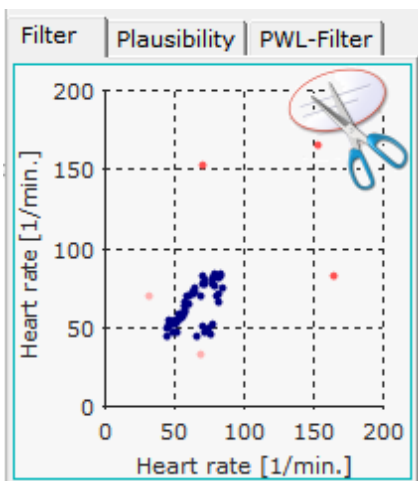
With these two manual editing steps of all of this measurement's quality problems can be corrected. The test is now ready for computing the HRV parameters.



Note: An artefact caused by a signal disturbance is not always the reason for sudden jumps of the heart rate. It might also be the case that the biosignal is correctly recorded, and the marks are all on the right positions. In this case the presence of the jumps may indicate an arrhythmia. It is not unusual to find occasional ectopic beats, which can be treated as artefacts. If the arrhythmia is too frequent, the HRV measurement becomes less reliable. In the case of atrial fibrillation, for instance, the HRV measurement is of no value.

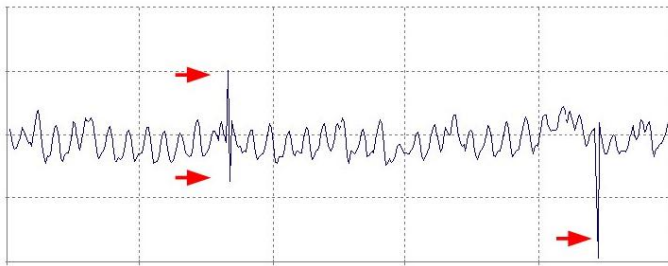
Step 4: Graphic filtering

Graphic filtering



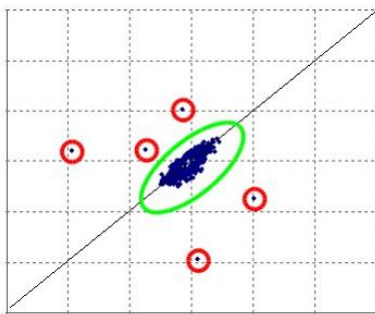
A HRV analysis should only include heartbeats that are under the control of the vegetative nervous system. Heartbeats that occur as a result of rhythmic disturbances distort HRV and usually lead to excessive HRV values, which can be mistakenly misinterpreted as a well-functioning neurovegetative regulation. A good way to separate "good" from "bad" heartbeats is to use the Poincare diagram. Neuroregulation-induced heartbeats are arranged along the bisector lines in the Poincare diagram, whereas heartbeats due to rhythm disturbances have an irregular pattern.

Example:



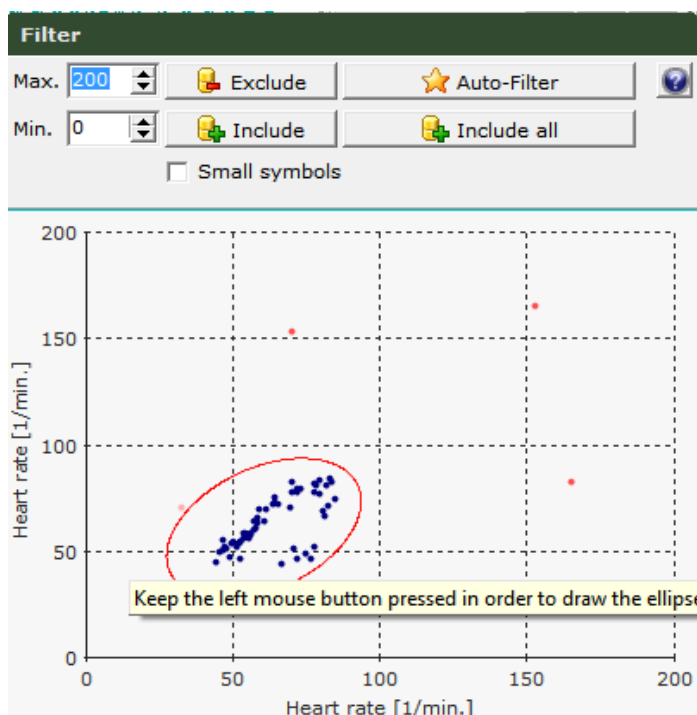
There have been some irregular heartbeats in the heart rate pattern, so-called extra-systoles, recognizable by the sudden changes in heart rate (red mark).

In the corresponding Poincare diagram the irregular heartbeats can be seen even more clearly:



Heartbeats as a result of vegetative regulation arrange themselves as point cloud along the bisector (green ellipse). Irregular heartbeats differ from this distribution pattern and can easily be identified (red circles). The special feature of the Poincare diagram, to distinguish regular from irregular heartbeats, allows for optimal filtering of the heart rate.

Poincare based filtering



To remove the irregular heartbeats, simply drag an ellipse around the point cloud that is formed by the regular heartbeats.

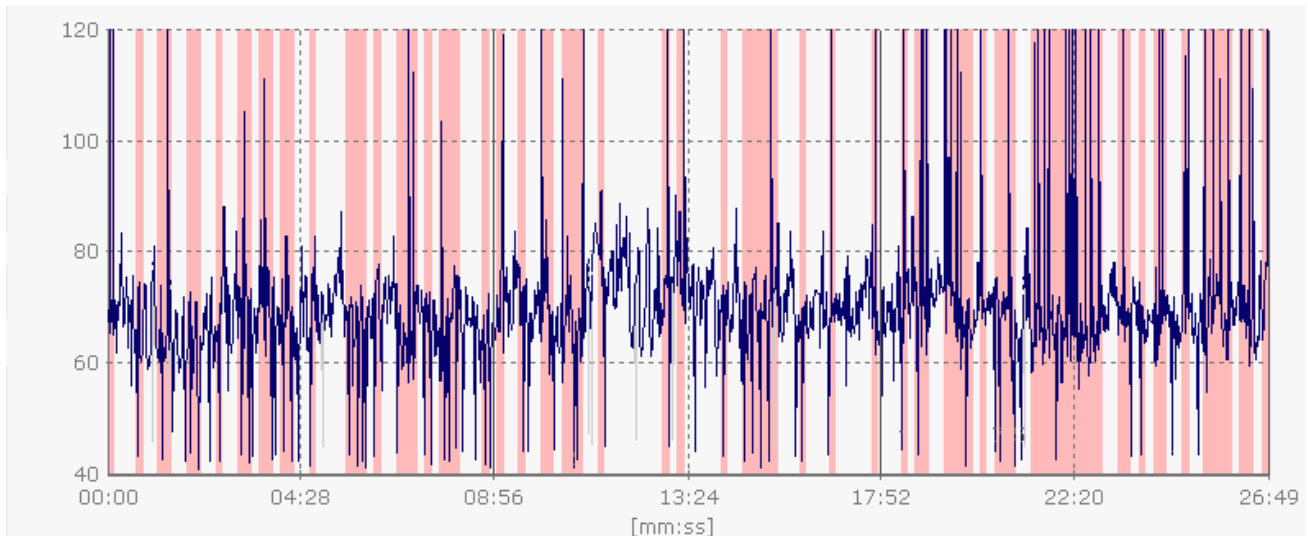
Click the "Exclude" button to remove all heartbeats outside the ellipse.

With the "Include" switch, you can record heartbeats back into the HRV analysis if accidentally excluded regular heartbeats.

Note: "Auto-Filter" takes the drawing of the ellipse and automatically calculates which heartbeats should be marked as artefacts and excluded during the evaluation. "Include All" causes an undoing of the graphic filter.

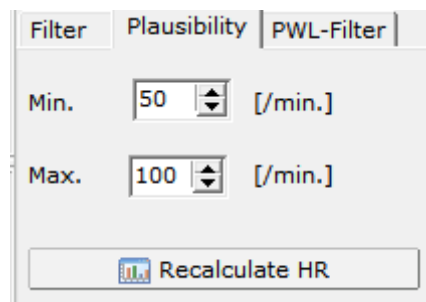
Step 5: Adjust plausibility check and heart rate filters


For longer measurements, it may be very time-consuming to process each individual artefact manually. For example, the following measurement contains numerous artefacts in approximately 30 minutes of measurement time.



Since this is an import of a RR interval based measurement, there is no biosignal in which the automatic heartbeat detection could be optimized (as described in step 1). In the case of shaky measurements with poor signal quality, such heart rate sequences can also be obtained, even with optimized heart rate detection.

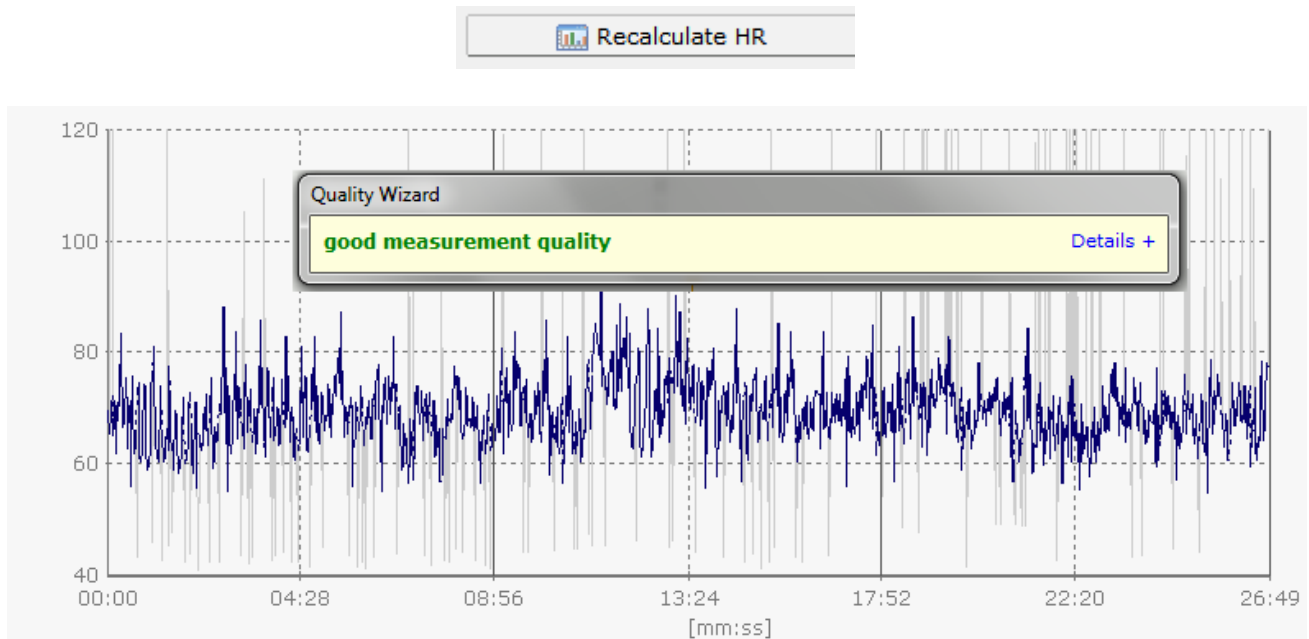
It is recommended to adjust the plausibility check of the HRV-Scanner.



Filter	Plausibility	PWL-Filter
Min.	50	/min.
Max.	100	/min.
 Recalculate HR		

Because the heart rate fluctuates between 90 and 55 in the example, a very good result is already achieved with plausibility values of 50/100.

For the changed settings to take effect, press the Recalculate Heart Rate button.



As can be seen in the picture, the adaptation of the plausibility check has already been sufficient in the example in order to produce a good data quality.

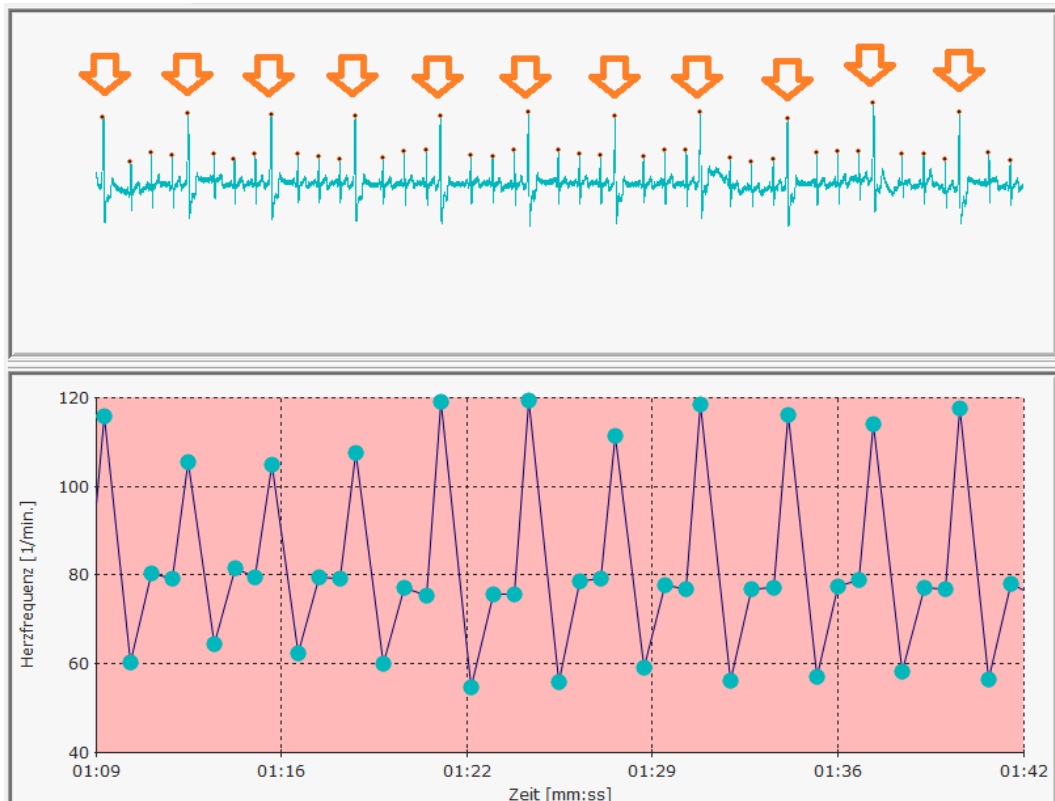
What happens during plausibility checks? In the plausibility check, the HRV-Scanner compares for each interval between two heartbeats whether the resulting heart rate is above or below the set limit values. If this is the case, the HRV-Scanner sets a "break" in this RR interval. "Breaks" we already know from step 2, they prevent the calculation of the heart rate from a RR interval provided with a "break".

Note: If artefacts persist despite the plausibility check, these can be corrected manually (see step 2).

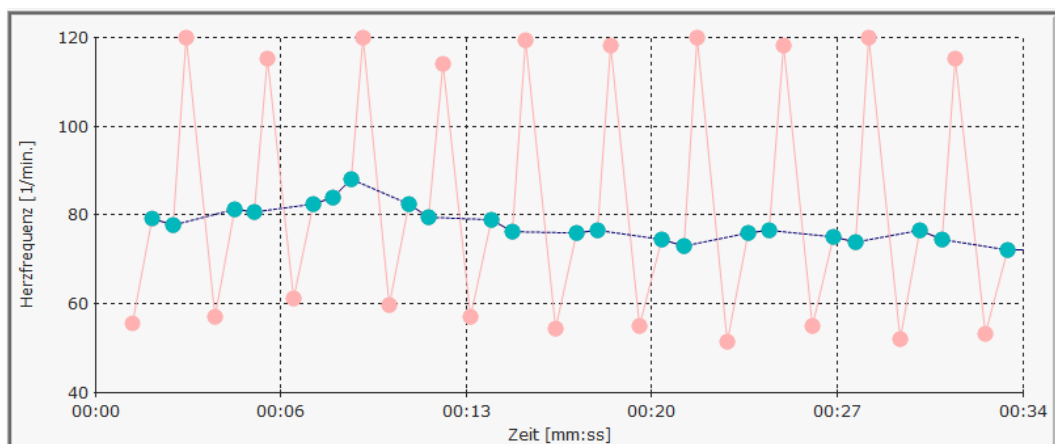
Limits of HRV determination

Heart rate variability, as the name implies, determines the variability of the heartbeat. This means that all kinds of artefacts (wobbling in the ECG due to movement, interference signals, ...) and heart rhythm disturbances (irregular heart beats, atrial fibrillation, ...) lead to an increased HRV. However, since this regulation does not come from the sinus node innervated by the parasympathetic nervous system, we cannot evaluate such heart rate profiles without first removing all artefacts and all heartbeats not from the sinus rhythm (excitation from the sinus node and not from accessory pacemaker cells).

Example 1: many irregular heart beats (marked in orange)

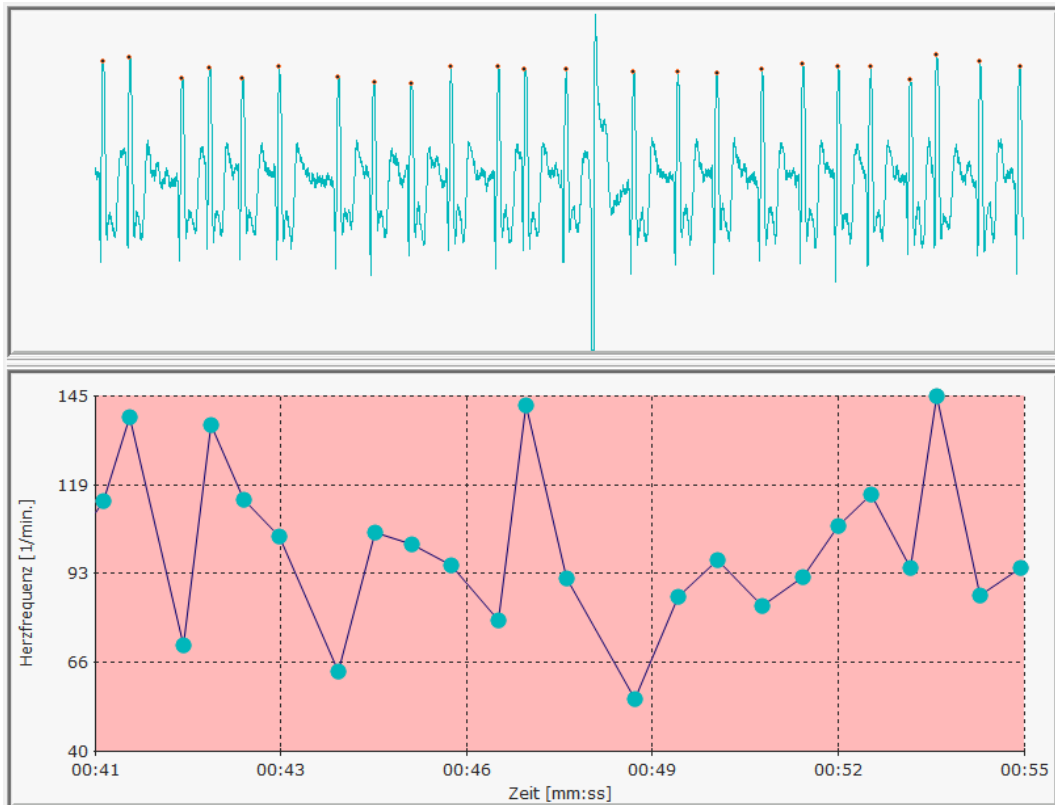


This shows the high variability in the heart rate curve due to the almost regularly occurring irregular heart beats (3 normal QRS complexes as signs of excitation from the sinus node, then always an irregular heart beats with compensatory pause afterwards).

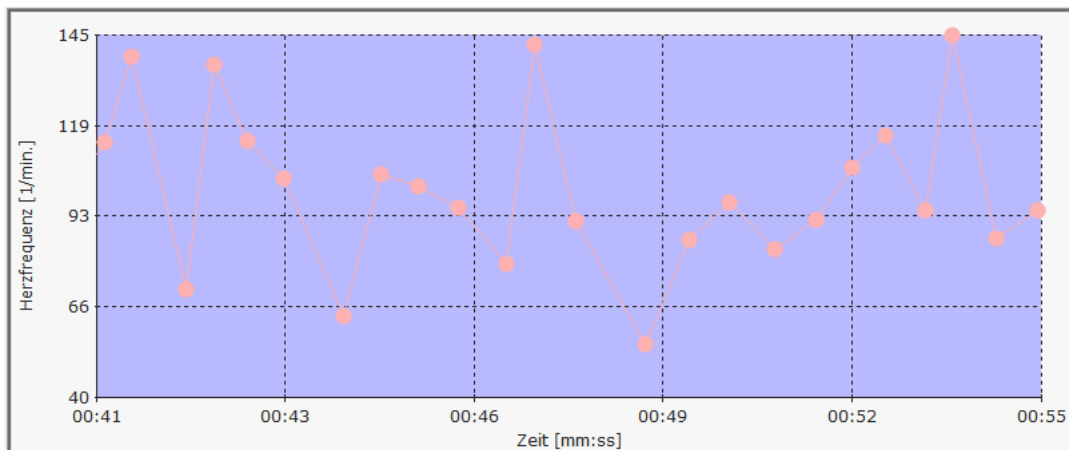


The heart rate after automatic filtering in the Poincaré filter. After exclusion of the irregular heart beats (pink dyed), approximately 50% of the heart rate (green) remain for the evaluation. For a 5 minute Short-Term HRV measurement, this is just sufficient to determine the HRV.

Example 2: Atrial fibrillation



At first glance, a regular ECG is available. One would assume here only one extra heart beat. However, a very disordered rhythm is observed when the heart rate curve is considered. This can be seen in the present atrial fibrillation. In the ECG, the missing P-waves are also seen as a sign of a non-regular atrial innervations.



The heart rate after automatic filtering in the Poincaré filter. After exclusion of the irregular heart beats (pink dyed), nothing of the original heart rate curve remains for the evaluation. Thus, a determination of the HRV is not possible or useful in the case of present atrial fibrillation.

The detection of such rhythm disturbances often requires some experience. If you have any doubts, please feel free to use our support.

A good quality ECG is always important for a reliable analysis. Only with this it is possible to get a more detailed picture of the present rhythm disturbances. This is not possible either with the pulse wave or with an RR distance-based HRV measurement (chest belt without ECG).

Basis HRV measurements

The two basic HRV measurements are Short-Term HRV and Deep Breathing Test. By combining both measurements, the current state of the vegetative regulation can be reliably determined.

These two measurements are very suitable for initial and follow-up investigations.

Starting with the 5-minute Short-Term HRV for recording the actual HRV in rest. The subject should lie relaxed for 5 minutes or sit if not possible (please lift up the legs to minimize the orthostatic load).

After the Short-Term HRV, the Deep Breathing Test is performed. This is a 1-minute functional test of the parasympathetic.

The Short-Term HRV

The Short-Term HRV measurement is a trusted and clinically proven test for assessing heart rate variability at rest. The Short-Term HRV measurement should be performed with the ECG (and possibly additional pulse wave). Duration: pure measurement time 5 minutes, incl. preparation approx. 8-10 minutes

Prepare the measurement

As with any HRV measurement, the determination of the Short-Term HRV requires careful preparation of the subject. It should be ensured that all factors that could influence the neurovegetative balance are controlled or at least documented. These include: medication, current illness, strong physical exertion (sports) in recent days, or even coffee or nicotine just before the measurement. Before the measurement begins, the subject should be in the final lying position for a few minutes to allow vegetative resting.

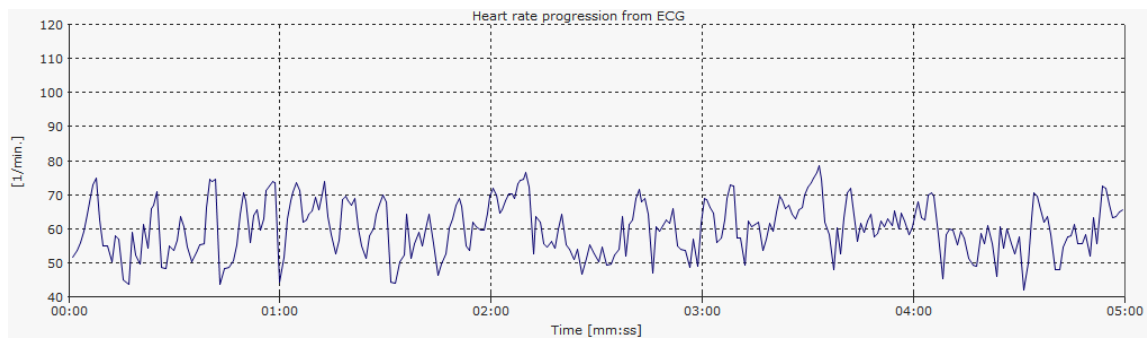
Perform the measurement

During the short-term measurement, ensure that the subject is quiet and breathes normally. The Short-Term HRV measurement should preferably be performed with the ECG. After the measurement time has elapsed, you will receive a message about the successful recording of the measurement. Close the measurement window. The measurement data are moved to an archive and an entry for the new measurement appears in the "Test and analysis" window.

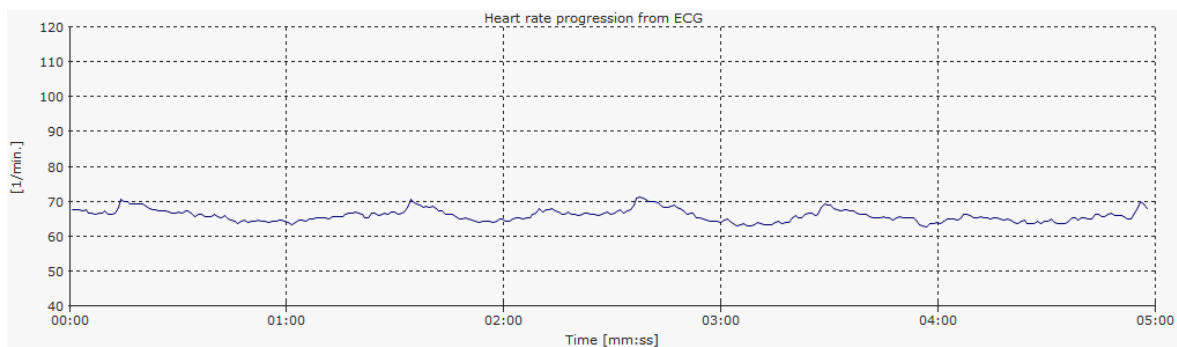
Evaluation

To do this, select the Short-Term HRV measurement in the "Test and analysis" window with the mouse and press "Analyze" or double-click on the measurement symbol. The course of the heart rate should show a steady up and down during the short-term HRV, in which the heart rate should be within the normal range (60-80 / min).

The lower picture shows a typical course of the heart rate during a Short-Term HRV measurement of a healthy subject.

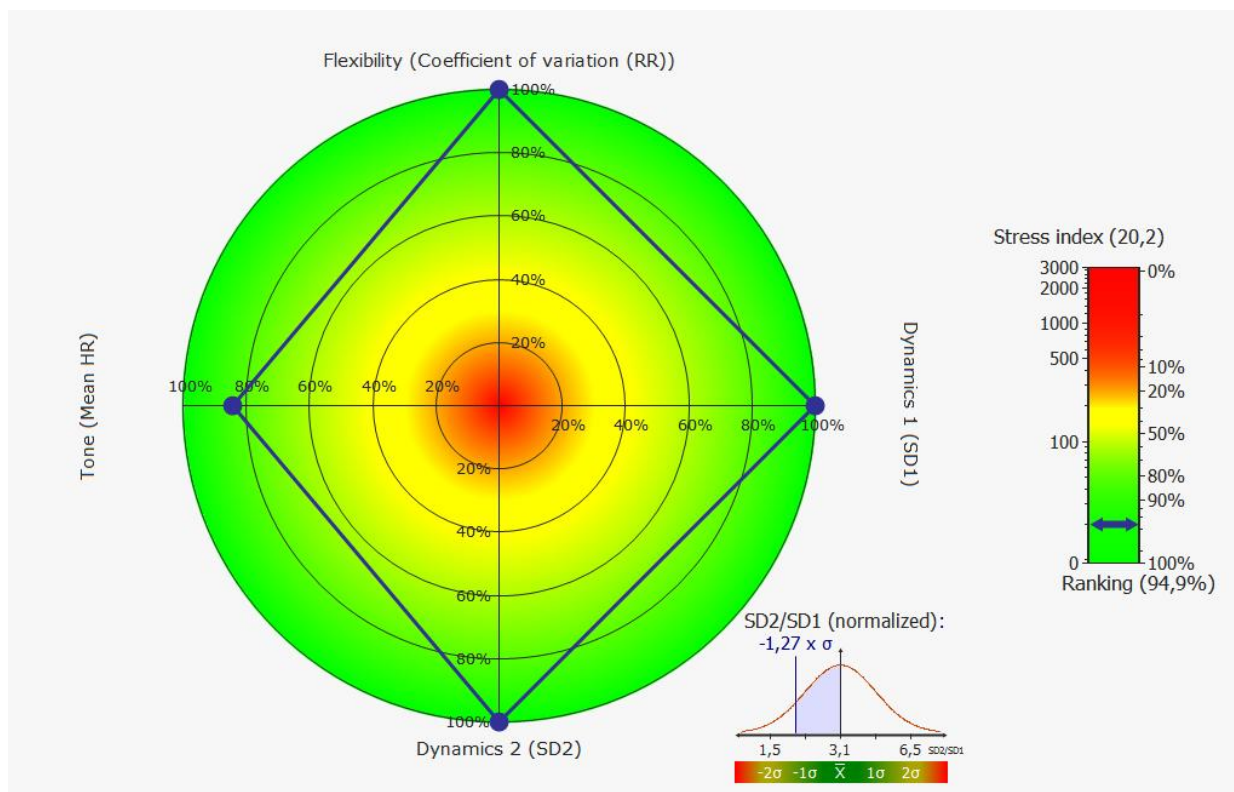


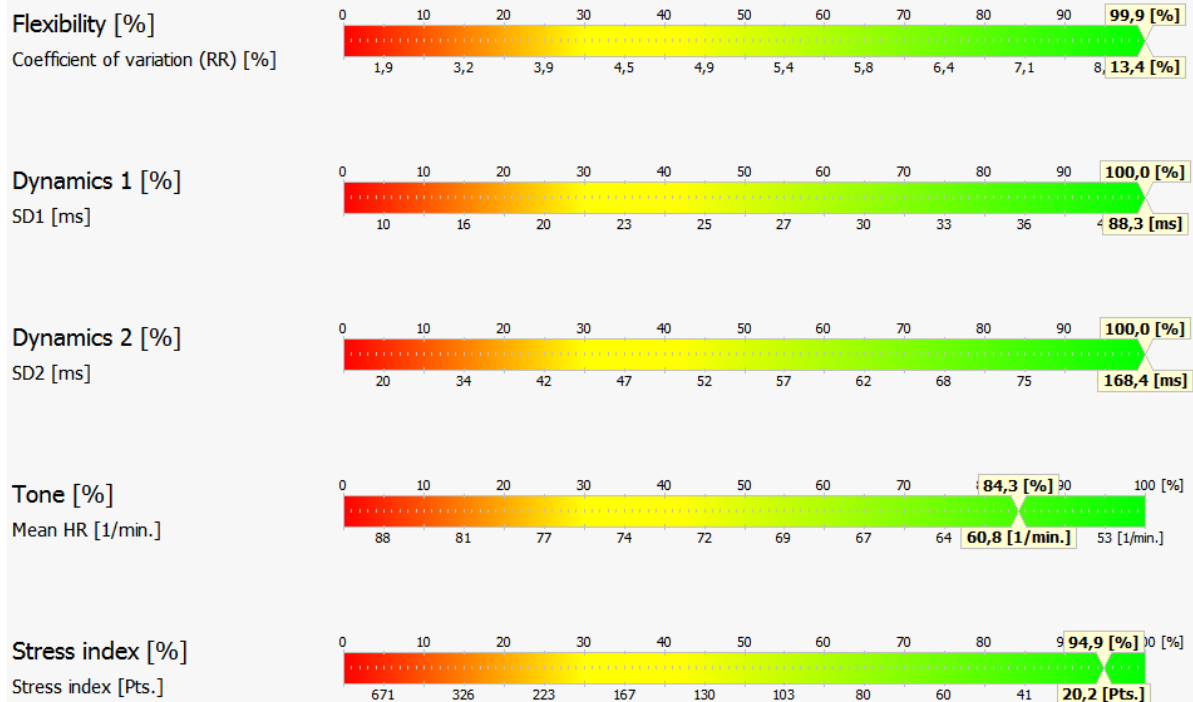
The lower picture shows a typical course of the heart rate during a Short-Term HRV measurement of a subject with markedly reduced heart rate variability.



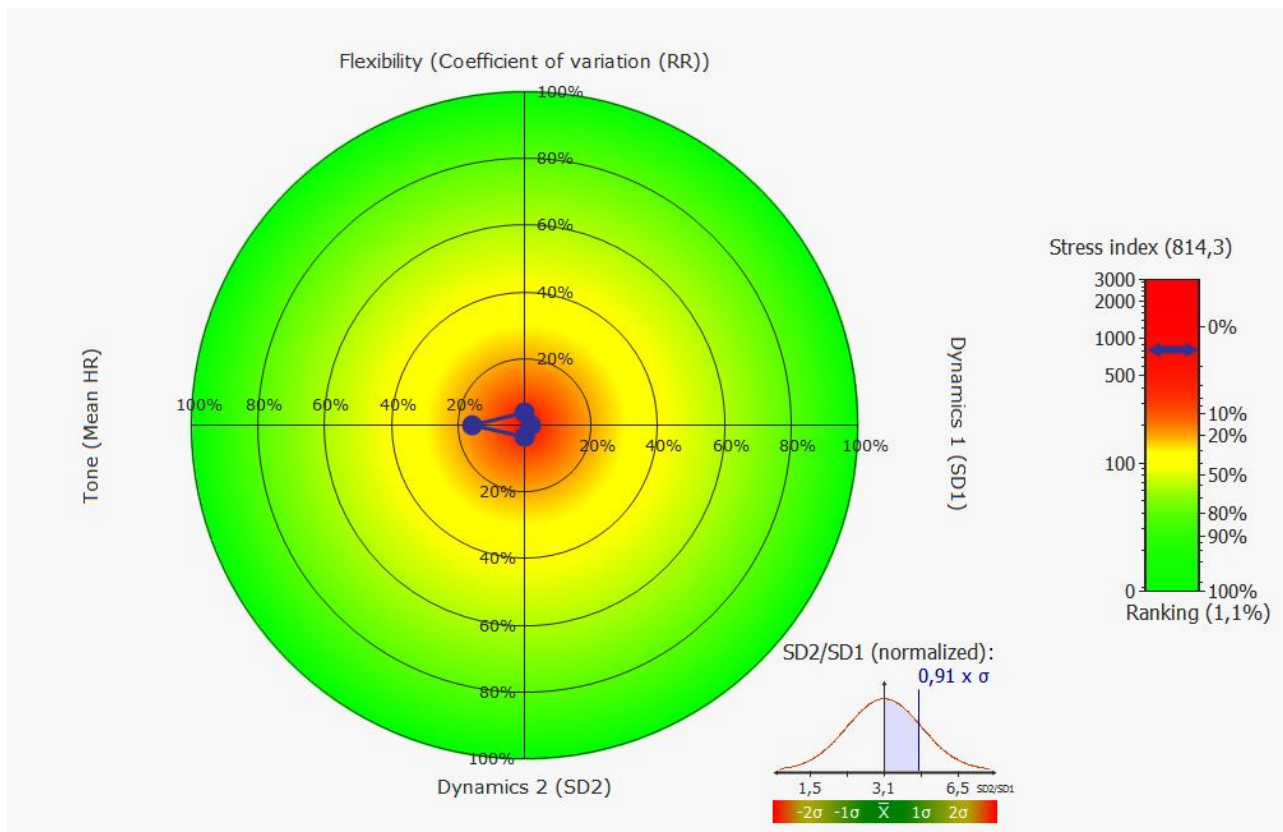
Standard values are stored for the most important parameters of the Short-Term HRV. This allows the comparison of the current measurement results with the results of healthy people of the same age.

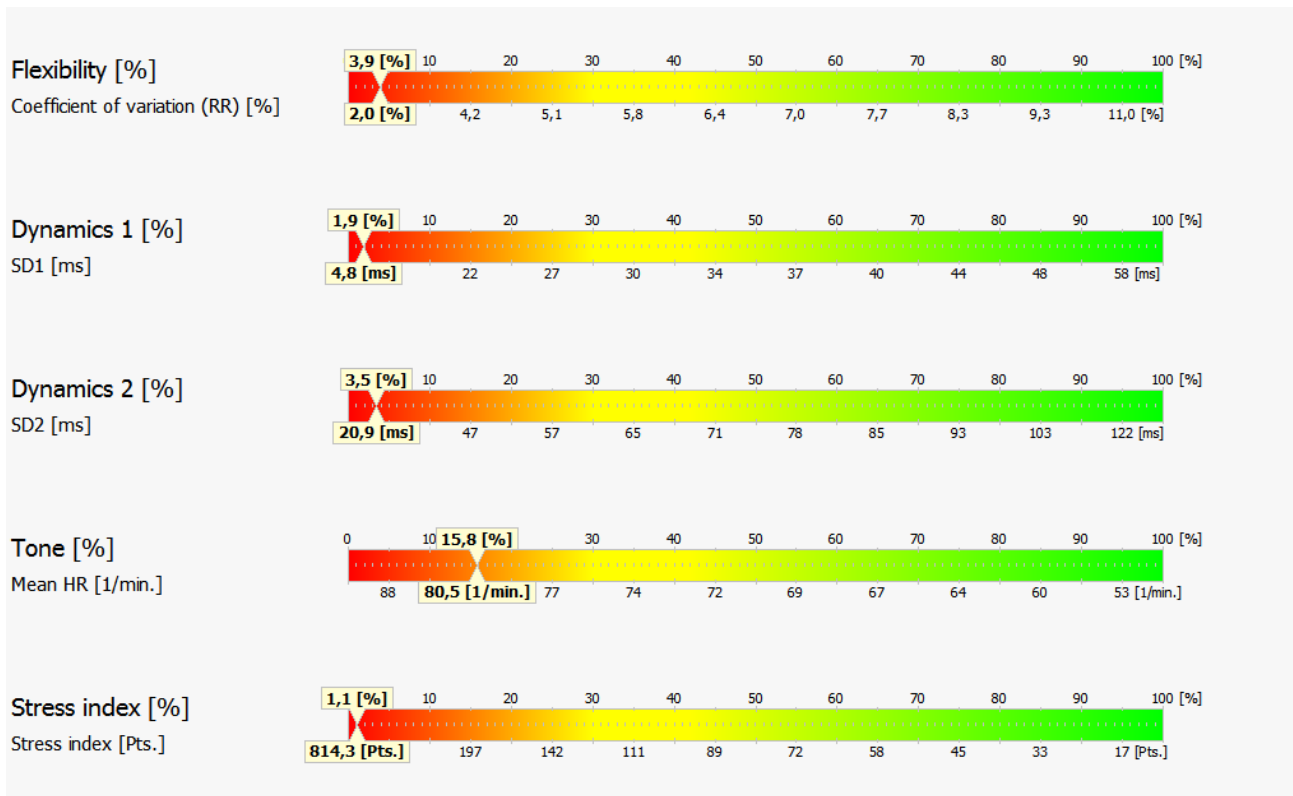
A typical result of a healthy subject could be as follows (spider web and bar graph):





The following pictures show a result of a subject with limited ability to regulate (spider web and bar graph).

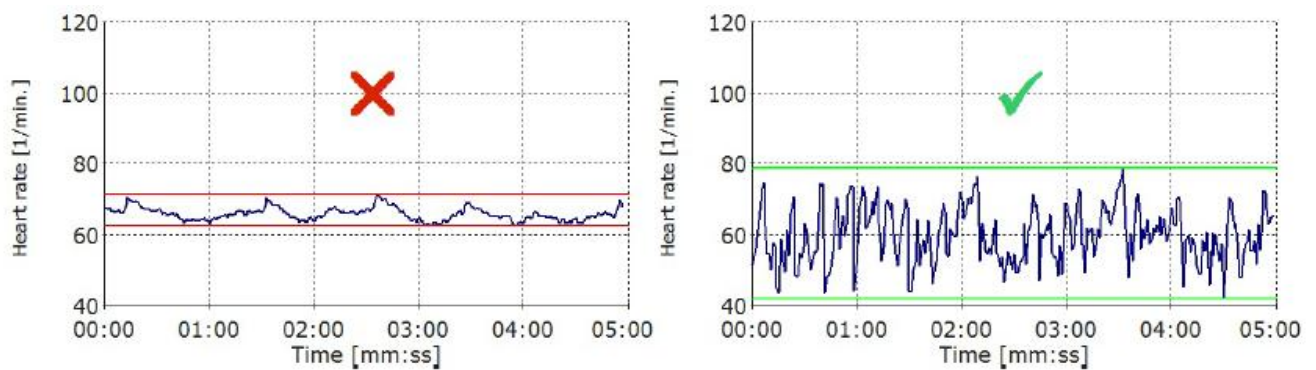




Target parameter in the rank diagram of the Short-Term HRV measurement

Flexibility (Coefficient of Variation RR)

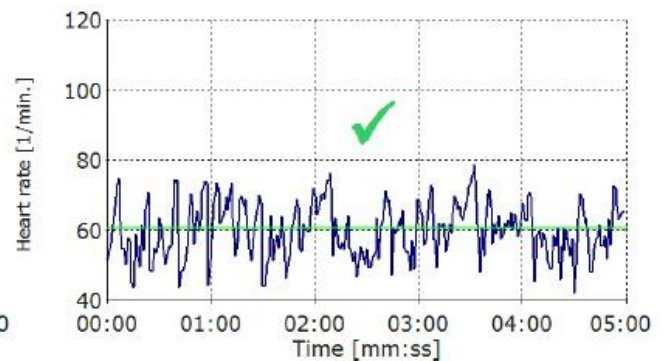
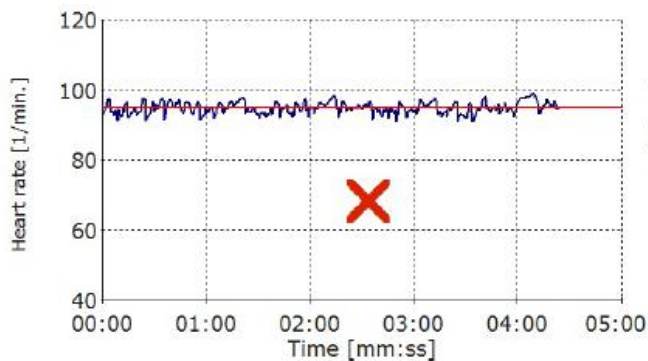
A sufficient adaptiveness is essential and is mainly achieved by a well-performing parasympathetic nervous system.



A high flexibility reflects a good adaptiveness of the cardiovascular system. Non-transient low values of flexibility indicate a weakness of the parasympathetic nervous system, which can affect your health adversely. Current events like infections, stress and strain can lower your flexibility temporarily.

Tone (mean HR)

Only a powerful parasympathetic nervous system can ensure a good regulation and enables our vital adaptiveness.

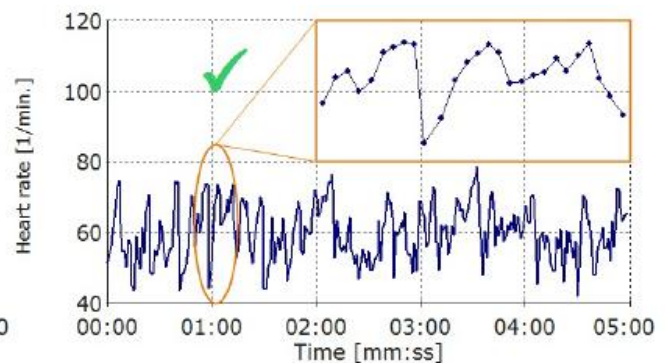
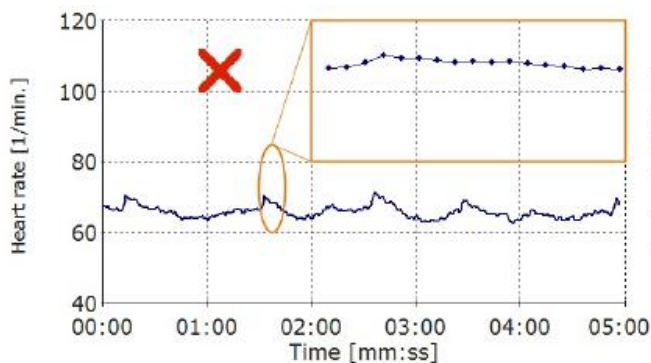


A good parasympathetic tone corresponds to a low heart rate. For example, people with a heart rate > 90 bpm have a clearly higher health risk compared to people with a heart rate < 60 bpm.

(HABIB, G.B. 1999. Reappraisal of heart rate as a risk factor in the general population. Eur. Heart J. Suppl. 1: H2-H10.)

Dynamics 1 (SD1)

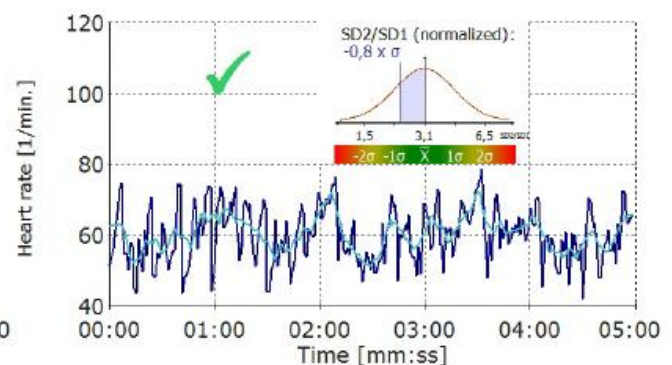
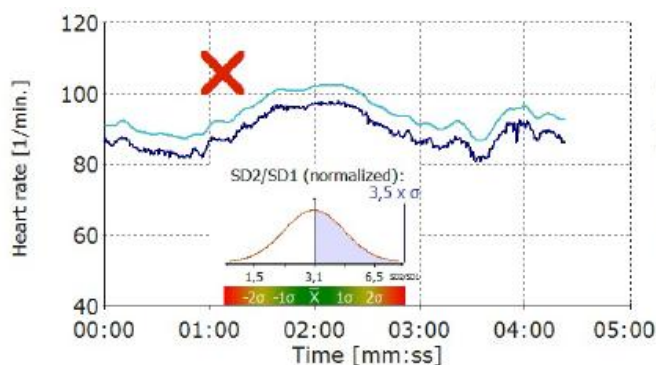
Fast fluctuations of the heart rate reflect a well-functioning 'inner brake'.



They are a sign of a fast information processing within the autonomous nervous system and indicate a good adaptability.

Dynamics 2 (SD2)

In addition to the fast heart rate oscillations there also occur slow heart rate fluctuations (light blue line).



Slow changes of the heart rate are caused both by the activity of the sympathetic 'accelerator' and the parasympathetic 'inner brake'. Their occurrence is therefore neither good nor bad. Nevertheless, slow and fast changes of the heart rate are normally in a certain relation, expressed by the SD2/SD1-ratio. If the slow dynamics (SD2) outweighs the fast dynamics markedly, the influence of the parasympathetic system is too low

for an optimal regulation. A dysbalance between sympathetic and parasympathetic system can not be excluded in this case.

SD2/SD1 ratio

The normalized SD2/SD1-ratio indicates, whether a favourable or more unfavourable relation of slow to fast fluctuations of the heart rate exists.



For this purpose, an individual SD2/SD1-ratio is compared to the mean value of a reference group. From this data a normalized SD2/SD1-ratio is calculated. High positive values indicate a predominance of slow heart rate oscillations. The higher the value, the less likely it is, that it is a normal finding. Negative values indicate higher proportions of fast heart rate fluctuations and are more favourable. Exceptions are extremely negative values ($< -2.0 \sigma$), which can indicate a missing sinus rhythm, irregular heartbeats or not removed artefacts. (The normalized SD2/SD1-ratio is the deviation of the SD2/SD1-ratio from the mean value of a reference group, expressed as multiples of its standard deviation, $n = 832$, normal distribution achieved after age correction and taking the logarithm, Kolmogorow-Smirnow-Test $p > 0.2$; Lilliefors $p > 0.2$)

More info about the SD2/SD1 ratio can be find at the explanation of the parameters.

Stress index

The stress index is especially sensitive to the unfavourable combination of a low heart rate variability with a high heart rate.



The stress index correlates significantly with accepted risk scores. Very high values can indicate an increased cardiovascular risk.

Respiration and HRV

Influence of breathing on the results of the short-term HRV

In interpreting the results of short-term HRV, respiration is usually not considered, although it represents a significant source of heart rate variance. Breathing has a major influence on heart rate regulation, especially in resting conditions.

In contrast to the RSA measurement, the short-term HRV does not guide the breathing. It is precisely the goal of the short-term HRV to observe how the parasympathetic nervous system adjusts to the supposed resting conditions. For example, stress, anxiety and depression patients often cannot calm down. These patients often breathe quickly and shallowly with a resulting low HRV.

The strong influence of respiratory rate and depth on neurovegetative cardiac regulation has long been known. In particular, a deep and slow breathing (4-6 breaths per minute) leads to a maximum of respiratory sinus arrhythmia. Increasing respiratory rates are associated with a reduction in respiratory sinus arrhythmia. The age of the patient also plays an important role: with increasing age, the respiratory sinus arrhythmia is reduced. The figure exemplifies the influence of respiratory rate and age on heart rate variability in short-term HRV.

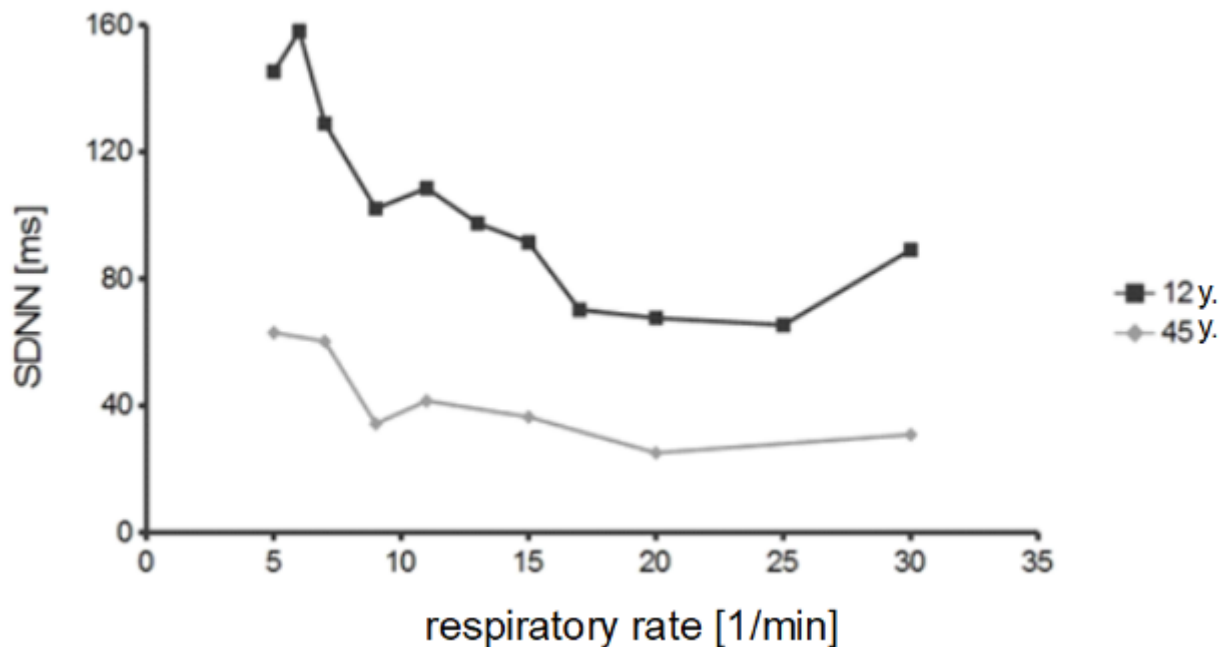


Fig. In both the child and the adult, the HRV increases with increasing Respiratory rate significantly.

We investigated in a study which respiratory rates occur during a short-term HRV and found a broad distribution of 4-23 breaths per minute. Due to the broad distribution, an influence of the respective respiratory situation on results of the short-term HRV must also be expected in everyday practice. For example, at high respiratory rates, especially in elderly patients, a low HRV result may occur. However, this does not necessarily imply an autonomic dysfunction; it can also be a physiological limitation of HRV due to rapid breathing. In the opposite case, a very low respiratory rate of 4-5 breaths per minute causes physiologically even higher amplitudes of the heart rate fluctuations but comparatively low RMSSD and SD1 values, because the coupled heart rate changes only slowly (RMSSD and SD1 measure rapid changes in the heart rate). It is therefore advisable to always consider the respiratory rate in the analysis of short-term HRV and to evaluate the HRV result in the context of respiration. In addition, it is recommended to always supplement the short-term HRV with an RSA measurement at 6 breaths per minute. Only with both tests a purely physiological restriction of HRV at high or very low respiratory rate can be differentiated from an actual parasympathetic dysfunction.

Our study has shown that mental stress leads to a significant increase in the respiratory rate in most subjects.

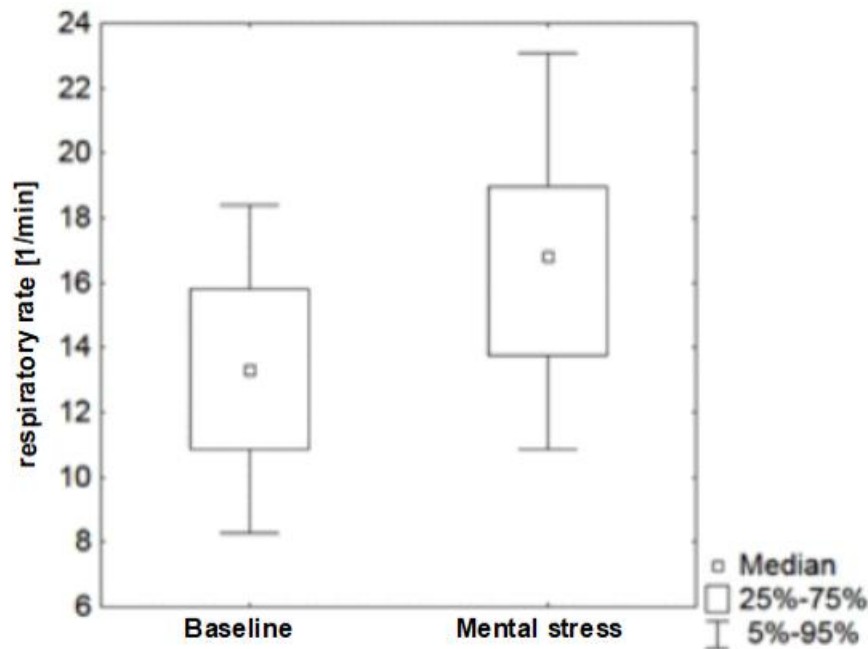


Fig. Respiratory rates at rest and under mental stress (stress by mental arithmetic)

It is also known that particularly anxious subjects respond to mental stress with an increase in the respiratory rate. The determination of the respiratory parameters during the short-term HRV can therefore be a diagnostic indication of the presence of a possible stress burden and should be recorded in addition to the HRV as a further physiological factor in stress and exercise examinations. If a stress and stress situation is present, the determination of the respiratory rate at rest would identify those patients who react to stress with a high respiratory rate. These patients would particularly benefit from breath-focused stress management training such as HRV biofeedback, meditation, and mindfulness-based stress reduction, as such training has a beneficial effect on respiratory rate at rest.

Distinguishing sympathetic - parasympathetic in the short-term HRV

The short-term HRV is primarily a parasympathetic functional test and does not provide diagnostically useful information about the sympathetic nervous system. At best, a detected parasympathetic dysfunction can be explained by an excessive sympathetic nervous system if signs of sympathetic activation such as high heart rate are present. Sometimes, however, an attempt is made to make a statement about the current activity of parasympathetic and sympathetic (vegetative balance). Previously used methods such as the LF / HF quotient and the SD2 / SD1 quotient cannot yet clarify this question satisfactorily. The regulation speed of the parasympathetic nervous system may be so high due to its physiology that its effect is on the regulation of the heart rate alone in the HF band of spectral analysis or a high SD1. However, with slow breathing, the parasympathetic nervous system can also regulate so slowly that its regulatory power, together with the sympathetic nervous system, lies in the LF band of spectral analysis or in a high SD2. So we see, for example a pronounced RSA with respiration of 6 / min. at 0.1 Hz in spectral analysis and thus in the LF band. A clear separation between the two actors of the autonomic nervous system in the LF band or SD2 is not possible in this case without consideration of the respiration.

An aid here is the assessment of the influence of the respiration on the heart rate, expressed as a percentage 0% to 100% (= maximum match of heart rate and respiratory curve). If there is a high influence of the respiration on the heart rate, then it is a RSA (respiratory sinus arrhythmia) and thus a primary parasympathetic regulation performance - no matter whether the peak is in the spectral analysis in the LF or in the HF range.

Conclusion

The assessment of HRV especially in the short-term HRV is incomplete without consideration of respiration. That's why we've included the respiration rating in the HRV scanner. Breathing is measured either via the respiratory curve from the ECG (so-called **ECG Derived Respiration**, EDR) or directly mechanically via a chest belt (only HRV-Scanner plus). Both methods are able to allow a sufficiently good assessment of breathing under resting conditions. For the EDR, a good quality ECG is required.

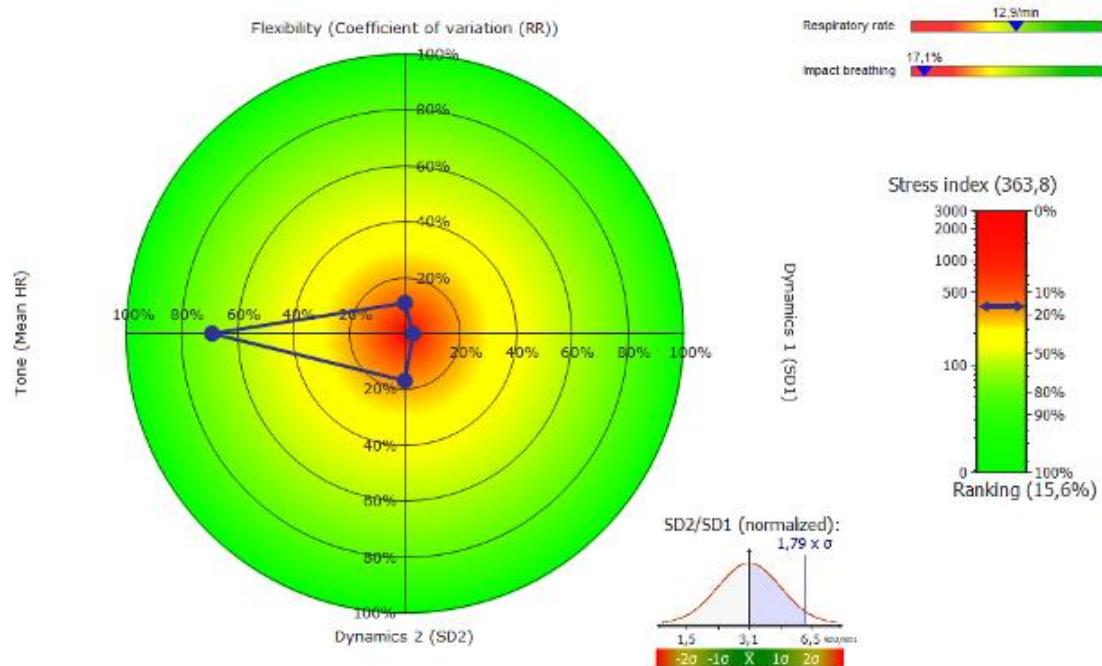


Fig. CAD patient with a pronounced parasympathetic dysfunction. Normal respiratory rate, yet hardly any respiratory sinus arrhythmia with severe limitation of the dynamic parts of the parasympathetic nervous system (SD1). Also not stimulative by deep breathing in the RSA measurement.

The evaluation graph of the short-term HRV shows both the respiratory rate and the influence of the respiration on the heart rate (right upper corner). Both parameters allow a more differentiated assessment of HRV.

The following points should be noted:

- High respiratory rates are often an indication of stress and stress situations and may be an explanation for a decreased HRV.
- Low respiratory rates cause slow regulation in the parasympathetic nervous system and lead to comparatively low RMSSD / SD1 values at high amplitudes (high SDNN or coefficient of variation).
- A high influence of the respiration on the heart frequency indicates the existence of a RSA and thus for a high activity of the parasympathetic. This is also evident in the LF band of the spectral analysis and in the SD2 at low respiratory rate.
- A slight influence of the respiration on the heart rate speaks against the existence of an RSA. This may indicate a lack of parasympathetic activity (especially if signs of sympathetic activation such as high heart rates) or high respiratory rates and mental stress.

Methods for measuring breathing

EDR - ECG Derived Respiration (HRV-Scanner standard and HRV-Scanner lite)

An indirect method of registering respiration is the derivation of the ECG's breathing signal, called ECG Derived Respiration, abbreviated EDR. For the EDR, one makes use of the fact that the diaphragm movement causes a slight change in the heart axis during breathing, which can be detected by the amplitude change of the R wave in the ECG (see Fig.).

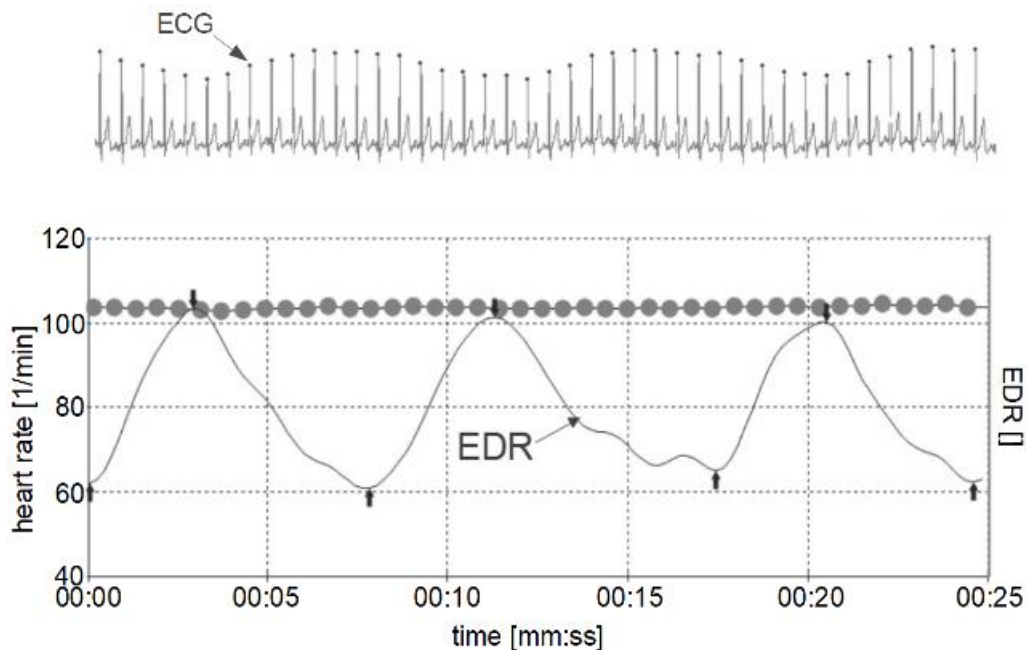
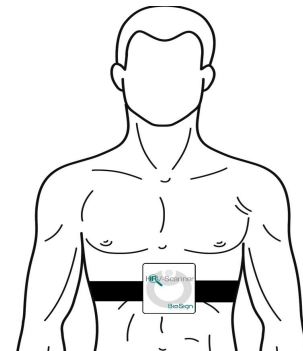


Fig. Breathing-synchronous changes of the heart axis occur due to the respiratory diaphragm movement, which lead to an alternating amplitude of the R-wave (upper curve). The lower image shows the corresponding heart rate curve and the breathing curve derived from the amplitude of the R-waves. (Note: The EDR curve was inverted in the HRV scanner in order to achieve an analogous course with the thorax movement.)

Mechanical determination of respiration - breathing belt (HRV-Scanner plus)

A chest strap measures the respiratory movement of the chest and determines breathing. The breathing belt is the gold standard for determining the respiratory rate in neuro-vegetative functional diagnostics.



EDR and mechanical sensors in the short-term HRV correlated with sufficient accuracy for an estimation of the respiratory rate using EDR ($r = 0.91$). For a precise analysis, however, a respiratory sensor is required because in individual subjects deviations in the respiratory rates of EDR and chest belt occurred up to 4 breaths per minute. Noticeable were non-respiratory fluctuations in the EDR signal, especially at lower respiratory rates, see figure below. Their origin is unclear. In addition to the diaphragmatic motion, there may also be other dynamic factors influencing the heart axis.

It is therefore recommended to visually inspect the EDR signal before interpreting the measurement result and to check for proper positioning of the inhalation and exhalation markers.

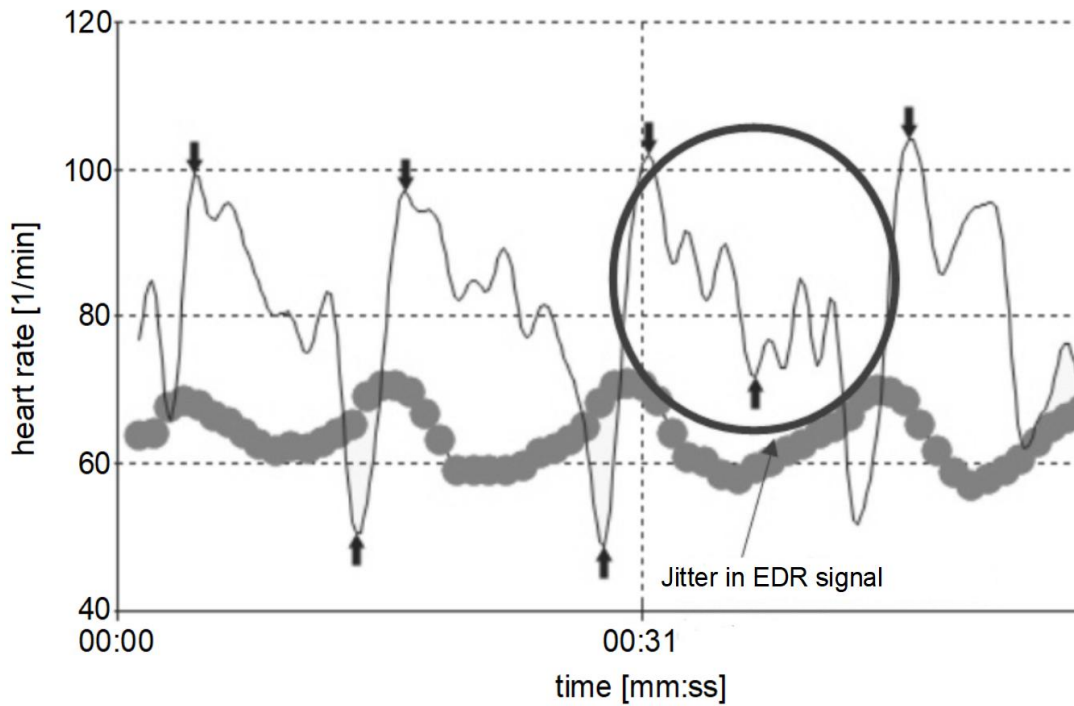


Fig. Errors in the EDR signal. It is not always possible to record a trouble-free EDR signal. Therefore, the EDR signal, and in particular the automatically set markings of the breathing cycles, should be checked for plausibility by the user.

The Deep Breathing Test

The Deep Breathing Test is a standard test in HRV diagnostics. The aim is the detection of the maximum available parasympathetic regulation (reserve). The Deep Breathing Test should be performed with the ECG (and possibly additional pulse wave). Duration: pure measurement duration 1 minute, incl. preparation approx. 5 minutes

The Deep Breathing Test (determination of respiratory sinus arrhythmia) reliably determines the current adaptability of our internal control system by means of a neurophysiologic test procedure, which has proven itself over the last four decades in medicine. A regularly performed measurement supports the identification of health risks, acute psychological and physical overloads and gives a positive feedback in case of successful lifestyle changes. The properties "Flexibility", "Tone" and "Dynamics" describe the three components of the "internal brake".

Prepare the measurement

As with any HRV measurement, the determination of the Deep Breathing Test also requires careful preparation of the subject. It should be ensured that all factors that could influence the neurovegetative balance are controlled or at least documented. These include: medication, current illness, strong physical exertion (sports) in recent days, or even coffee or nicotine just before the measurement. This measurement usually takes place while sitting, so that the subjects can better follow the breathing pattern on the screen. The Deep Breathing Test is a function test. The subject must actively participate. Decisive is the maximum deep inhalation and exhalation of the subject according to the guidance of the respiration pattern. Breathing should be practiced before the start of the measurement together with the subject. The blood volume displacement caused by the breathing forces the body to regulate. As a result of the measurement, we see how well the vegetative nervous system is capable of doing so.

Perform the measurement

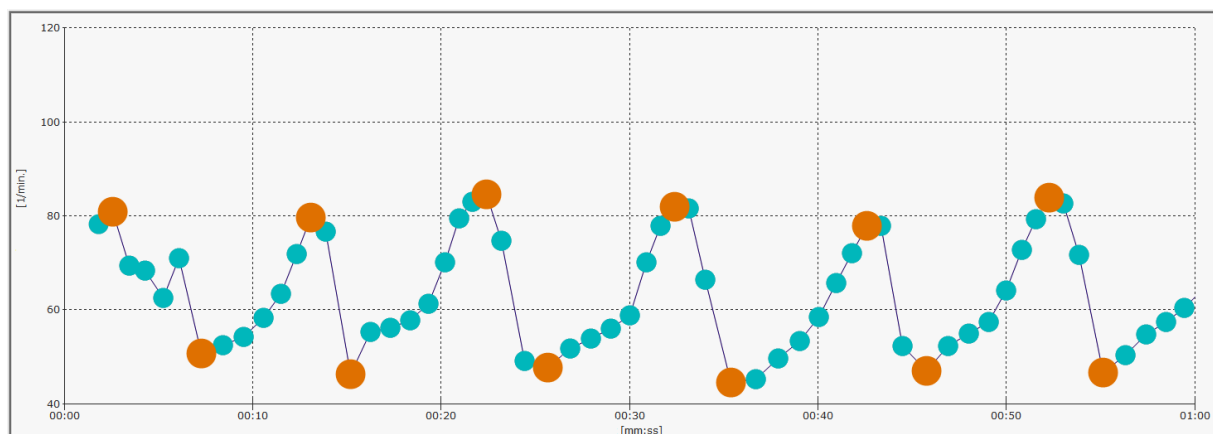
During the short-term measurement, ensure that the subject breathes deeply and evenly. After the measurement time has elapsed, you will receive a message about the successful recording of the measurement. Close the measurement window. The measurement data are moved to an archive and an entry for the new measurement appears in the "Test and analysis" window.

Evaluation

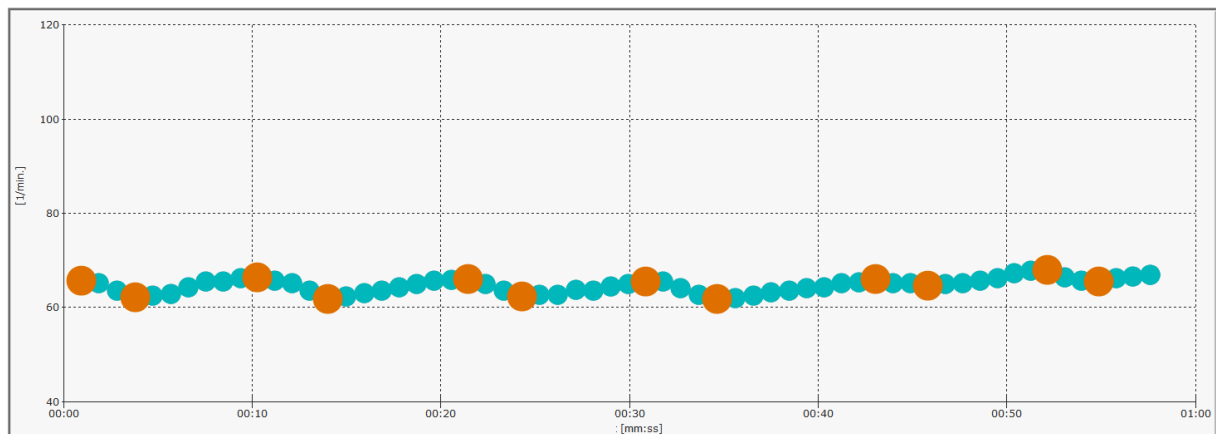
To do this, select the Deep Breathing Test carried out using the mouse in the "Test and analysis" window and press "Evaluate" or double-click on the measurement symbol.

The course of the heart rate during the Deep Breathing Test should show a steady breath-dependent up and down.

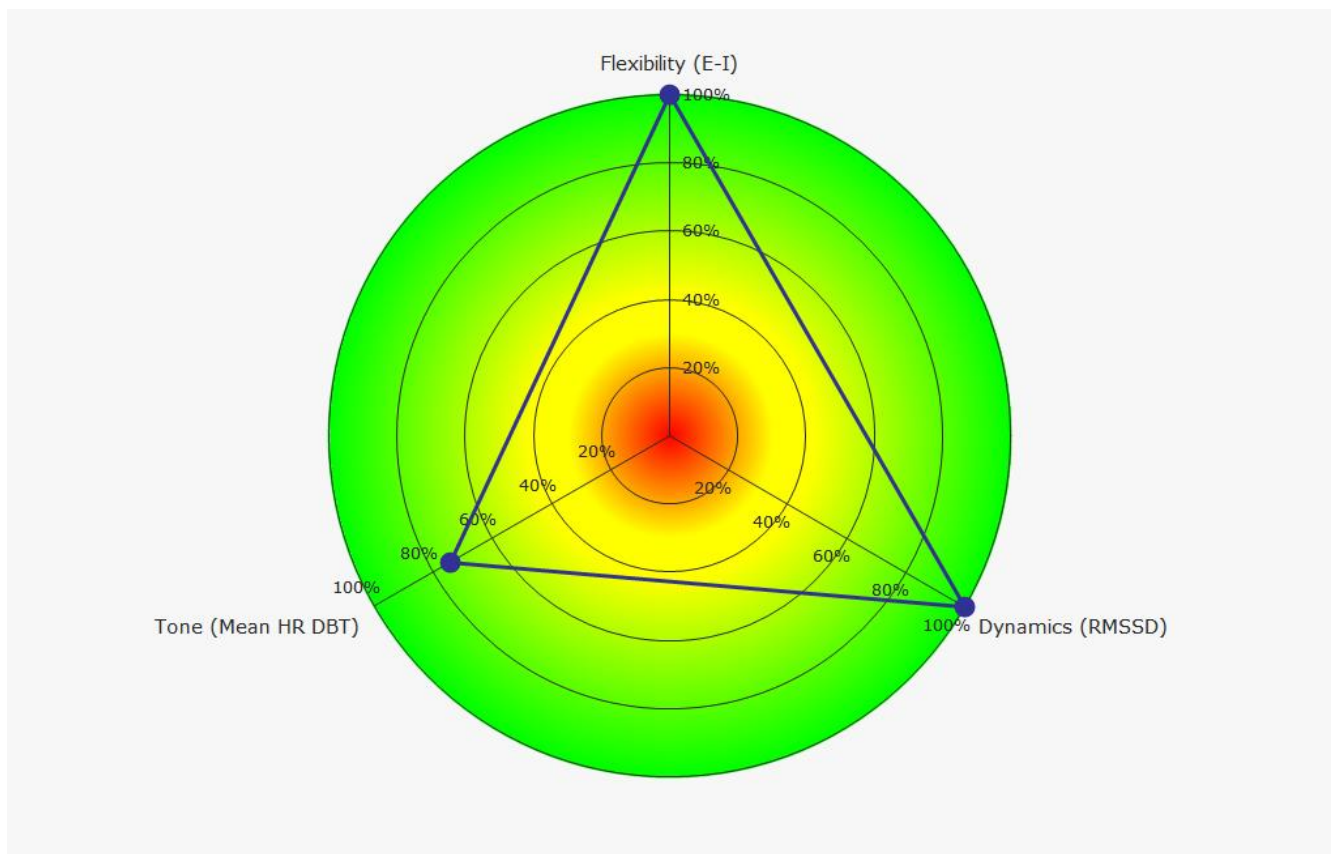
The lower picture shows a typical course of heart rate during a Deep Breathing Test of a healthy subject.

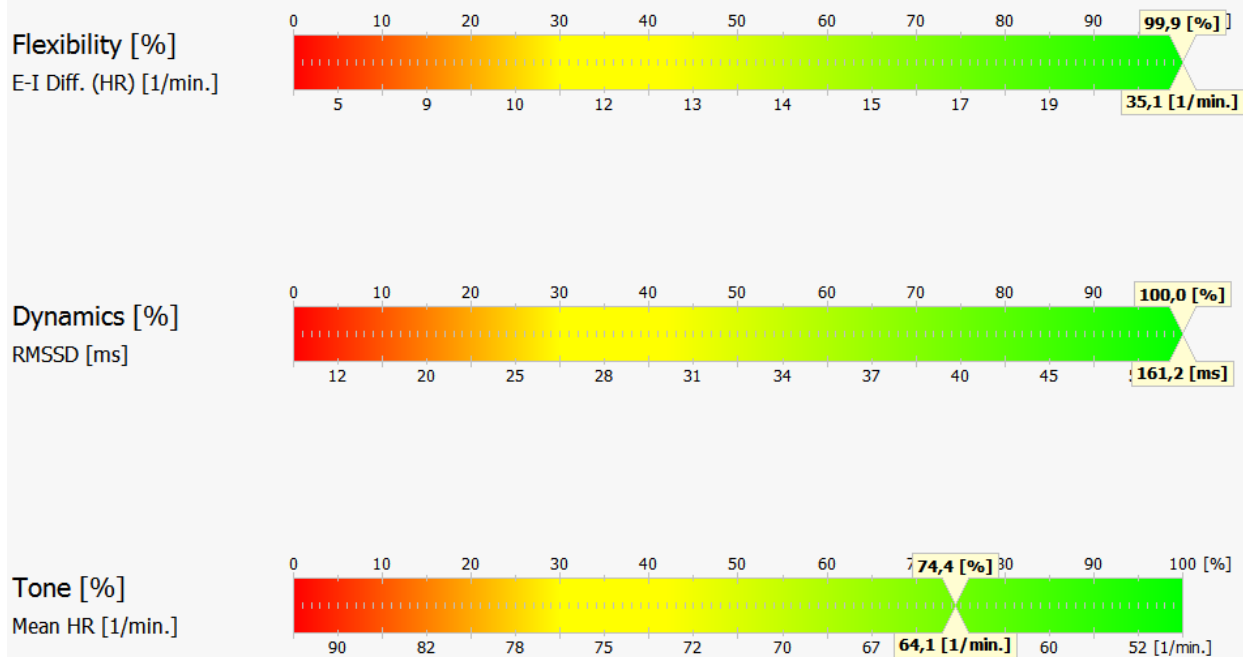


The lower picture shows a typical course of the heart rate during a Deep Breathing Test of a subject with significantly reduced heart rate variability.

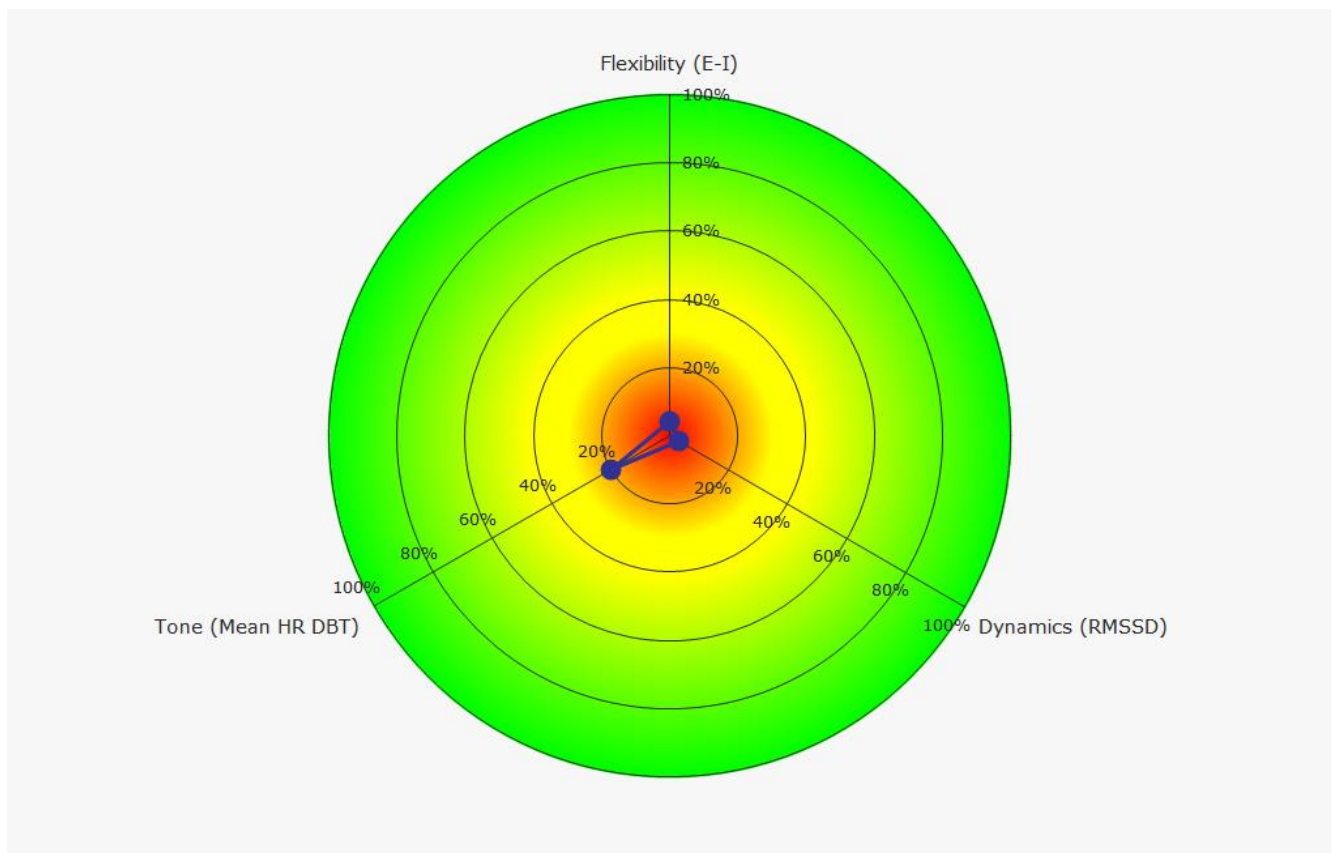


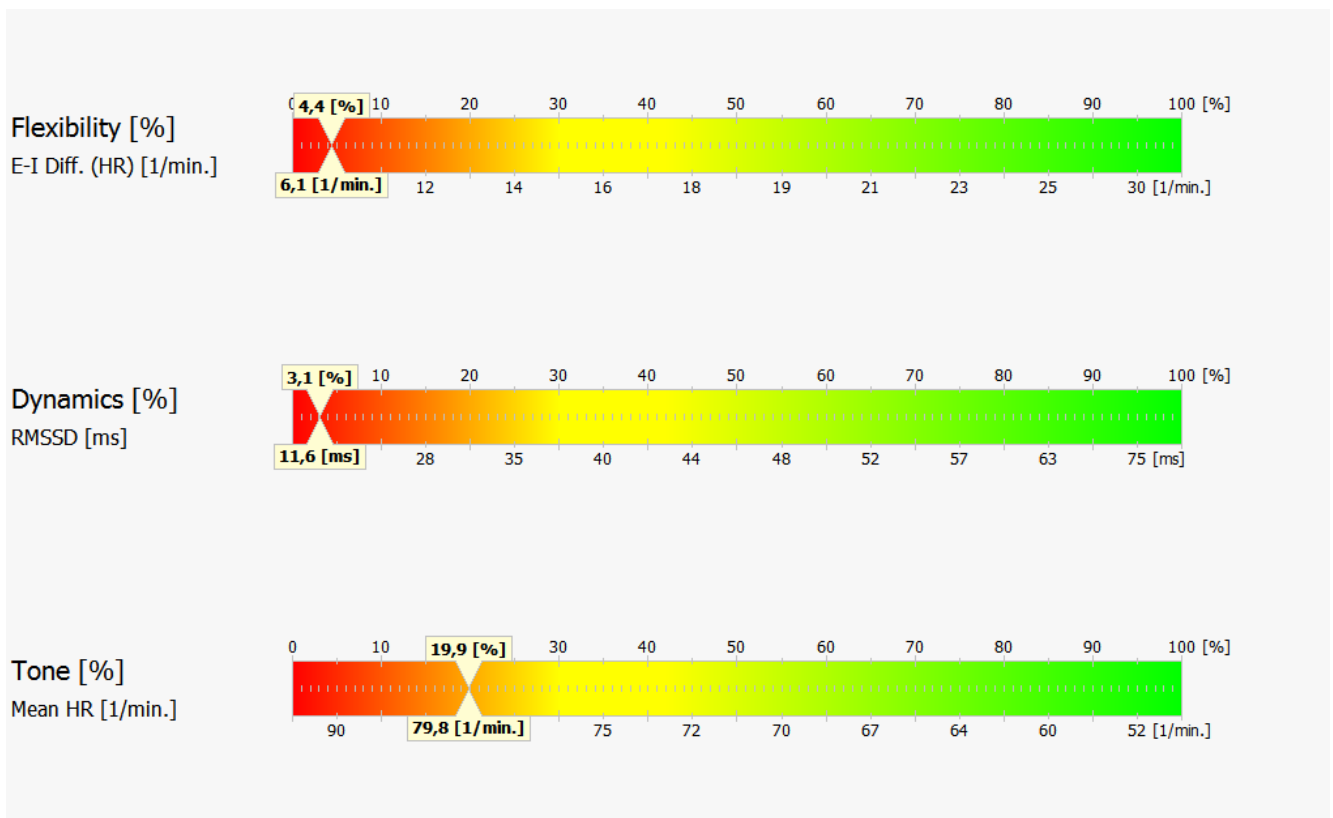
A typical result of a healthy subject could be as follows (spider web and bar graph):





The following pictures show a result of a subject with limited ability to regulate (spider web and bar graph).

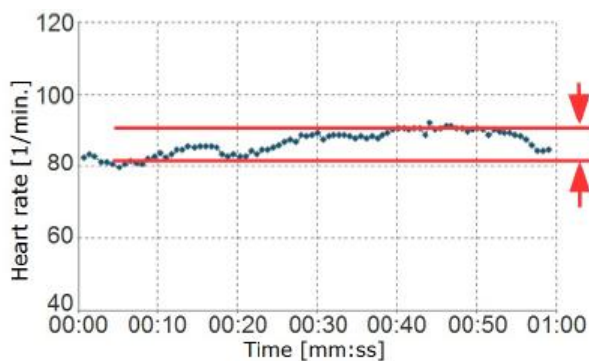




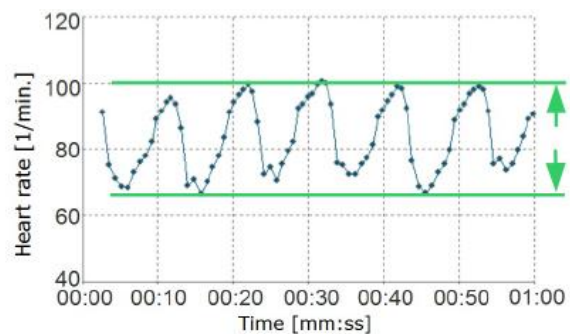
Target parameter in the rank diagram of the Short-Term HRV measurement

Flexibility (E-I)

„Survival of the fittest“. This often misunderstood sentence in the context of the Darwinian theory of evolution literally means the "survival of the best adapted". This adaptability, which is necessary for survival, is already an absolute must at the level of body regulation and is ensured by a well-functioning heart-brain axis. A high flexibility value reflects a good adaptability of our cardiovascular system. On the other hand, long-term low flexibility is an expression of a lack of adaptability. For example, a low degree of flexibility is a prognostically unfavourable sign after myocardial infarction *.



Example of a very low flexibility (heart rate fluctuation not existent)

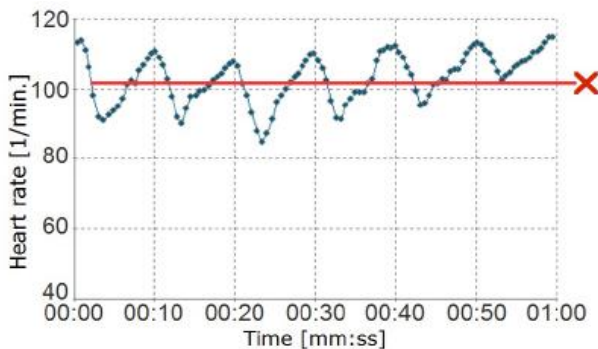


Example of a high flexibility (large amplitude of the heart rate fluctuation)

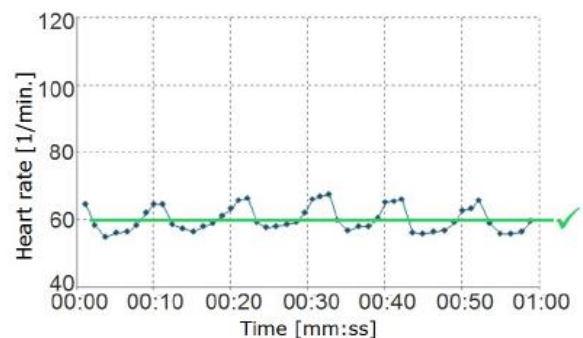
*A simple bedside test of 1-minute heart rate variability during deep breathing as a prognostic index after myocardial infarction. Katz A, Liberty IF, Porath A, Ovsyshcher I, Prystowsky EN. Am Heart J. 1999 Jul;138(1 Pt 1):32-8.

Tone

At rest our body-borne braking and regeneration system (parasympathetic nervous system) is the active part of our heart-brain axis. Only a powerful parasympathetic can control the body processes optimally and allows our life-long adaptability. A good parasympathetic root tone is expressed in a lower heart rate. For example, people with a heart rate > 90 / min have more than three times the risk of death than people with heart rate < 60 / min *.



Example for a low parasympathetic tone (high mean heart rate)

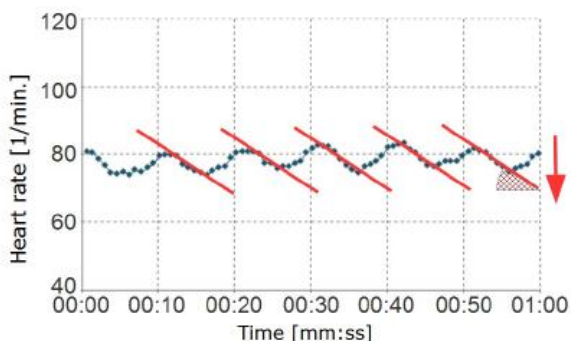


Example for a high parasympathetic tone (low mean heart rate)

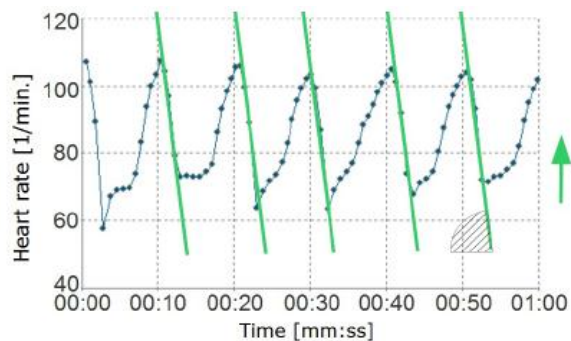
*HABIB, G.B. 1999. Reappraisal of heart rate as a risk factor in the general population. Eur. Heart J. Suppl. 1: H2-H10.

Dynamics

An essential feature of a powerful heart-brain axis is the speed with which the information processing and body regulation takes place. Similar to the braking test in the car, the faster the system comes to "standing", the more powerful is the built-in brake.



Example of a heart-brain axis, which has only a low dynamics. The heart rate changes only slightly from heartbeat to heartbeat.



Example of good dynamics. The heart rate changes very strongly during exhalation (decrease of heart rate)

Why two measurements as a basis HRV

Why do we recommend the combination of Short-Term HRV and Deep Breathing Test as the basis HRV measurement? What does the combined interpretation of the results of both measurements say?

Short-Term HRV	Deep-Breathing-Test	Description	Current HRV	Reserve HRV
+	+	Good results in Short-Term HRV - <u>and</u> Deep Breathing Test The parasympathetic regulation works well under stimulation and at rest. The vegetative nervous system is in equilibrium. We usually find such results in people who are resting, healthy and athletic, and usually have a good work/life balance or a good stress resilience.	+	+
-	-	Bad results in Short-Term HRV - <u>and</u> Deep Breathing Test The parasympathetic regulation does not work well either under stimulation or at rest. In most cases a chronic damage to the parasympathetic is already present. The reason for this is often a chronic process. (diabetes, chronic stress, ...)	-	-
-	+	Bad results in Short-Term HRV, but good results in Deep Breathing Test The parasympathetic regulation works well under stimulation, but badly at rest. This gives us an indication that in principle there is still a good capacity/reserve of regulation, but this cannot be used under resting conditions. Possible causes are: rapid flat breathing as a sign of mental stress. Such results can usually be seen in younger subjects who have previously had a good regulation but are currently being influenced by stress. The prognosis for recovering a well-functioning vegetative regulation is positive, since the regulatory system has probably not suffered any structural damage.	-	+

What has a negative impact on HRV

A markedly increased fasting blood glucose value leads to the assessment that a diabetes is present. In the case of HRV, the facts are unfortunately much more complex. How do we interpret poor results from our HRV measurements? Decisive is the knowledge about what can take effects on the HRV and the questionnaire (anamnesis). Combining both will quickly lead us to the cause of parasympathetic dysfunction, or the shifted vegetative balance.

Anticholinergic drugs

Anticholinergic drugs (antidepressants, ...) have a negative effect on HRV as they inhibit the transmission of information in the parasympathetic nervous system. These medicines can be identified with the following side effects (see leaflet): mouth dryness, slight visual disturbances, constipation, dry eyes, urinary retention.

Drugs with anticholinergic action

Drug group	Examples
Antiemetics, Antivertiginosa	Dimenhydrinat, Promethazine, Scopolamine
Drugs for Parkinson's disease	Benzatropine, Biperidene, Trihexyphenidyl, Metixen
gastrointestinal spasmolytics, inhibitors of secretion	Butylscopolamine, Pirenzepine
urological spasmolytics	Oxybutynine, Tolterodine, Fesoterodien, Darifenacine, Solifenacine
Intensive care, preoperative medication	Ipratropium, Tiotropium, Aclidiniumbromid
Mydriatics	Atropine, Scopolamine, Homatropine, Tropicamid
Intensive care, preoperative medication	Atropine

Further information

You can find an overview under <http://www.hrv24.de/HRV-Medikamente.htm> (no guarantee).

Food / Drugs:

(e.g. caffeine, nicotine, alcohol)

Chronic diseases

(e.g. diabetes, Parkinson's disease, depression)

Acute diseases

(e.g. flu, heart attack)

Excessive sports, over training

Any kind of sporting overload will result in a temporary reduction of the individual HRV. For this reason, the HRV measurement can also be used to monitor exercise in sports.

Stress

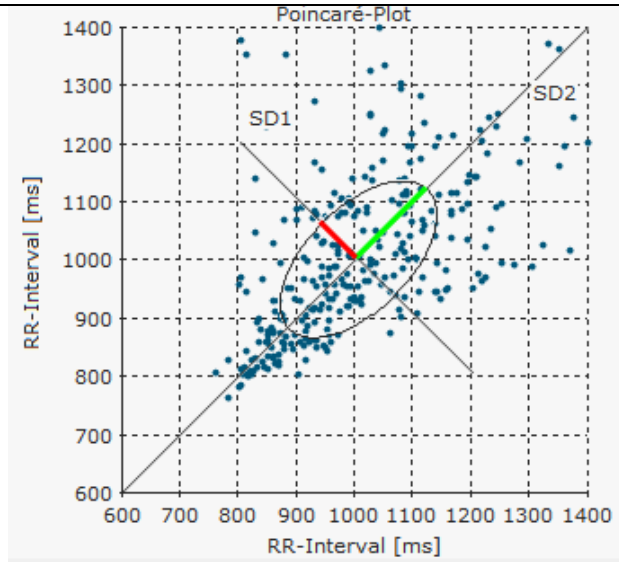
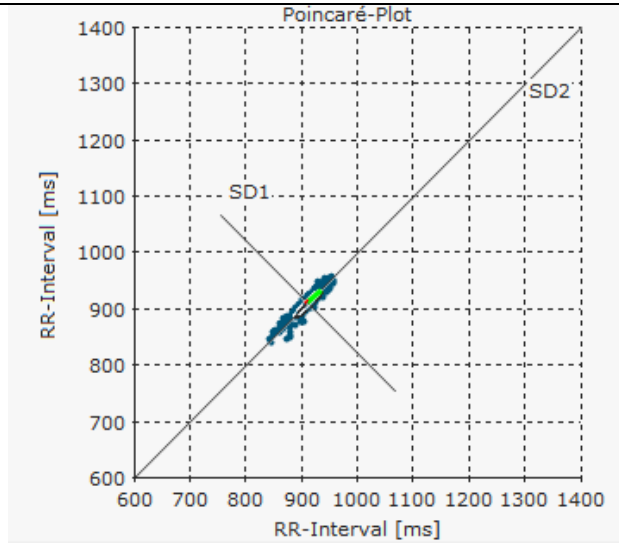
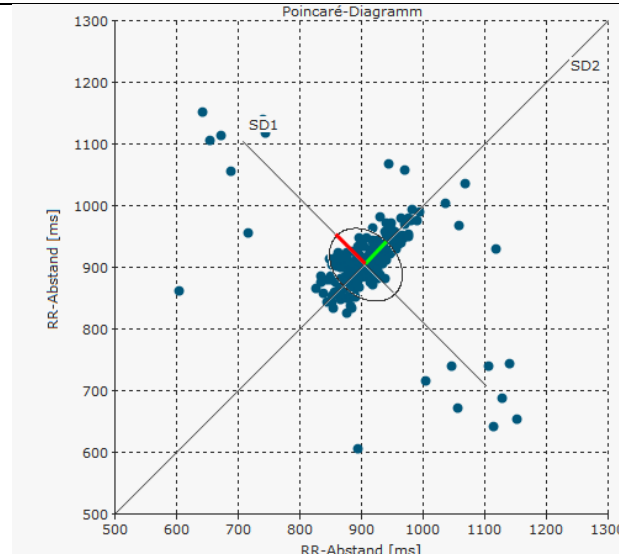
Acute and chronic stress often has a marked negative impact on individual HRV. The extent depends on:

- individual sensitivity for stress
- quality of the stress
- duration of stress

Further diagrams in the analysis

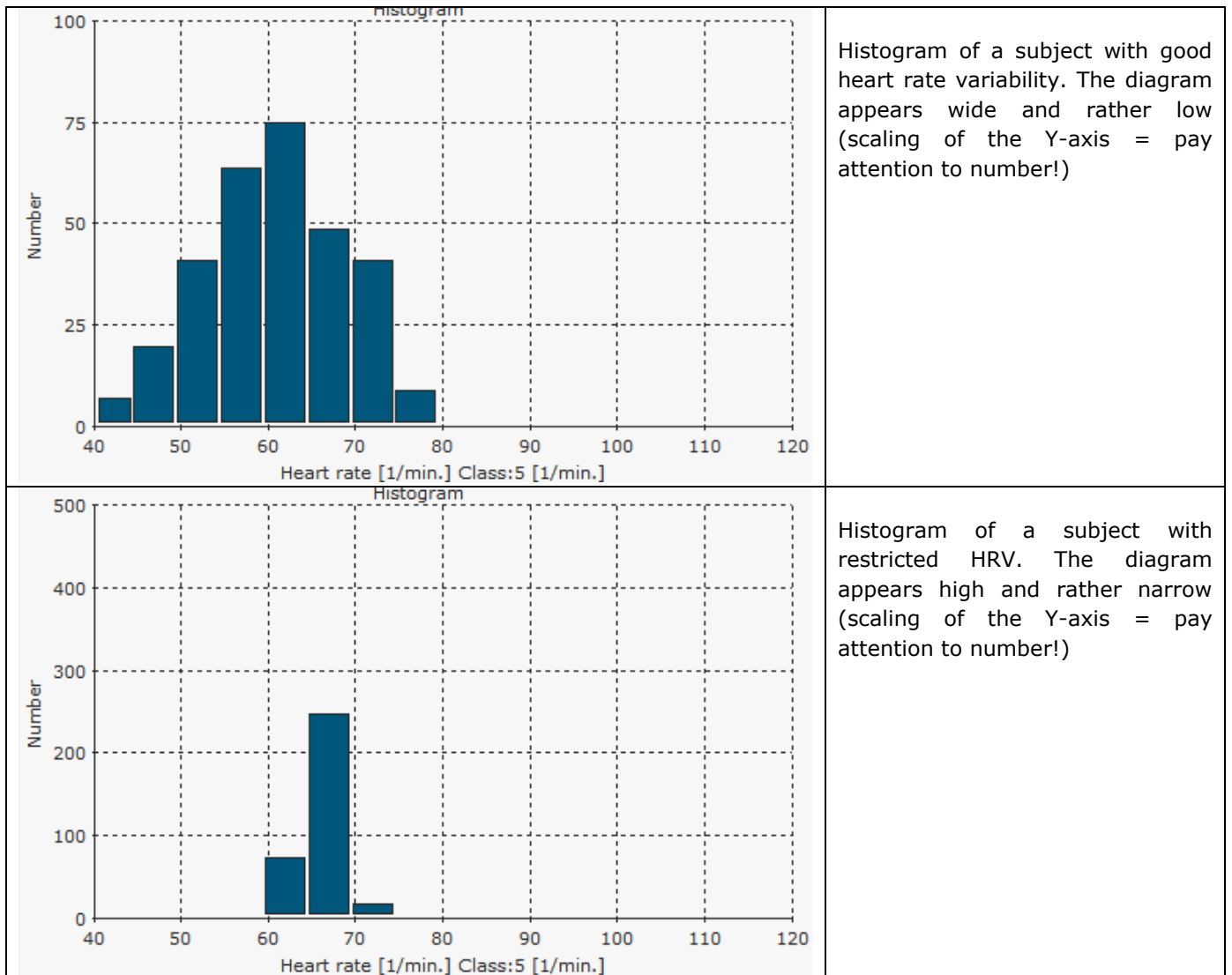
Poincaré Plot

The Poincaré Plot (Lorenz Diagram, Scatter Plot) was named after Henri Poincaré (1854-1912). Here, each RR interval (or heart rate) is plotted against its successor. This produces typical patterns that represent periodicity and similarity.

	<p>In the case of HRV, with good variability and periodicity, typically a point cloud is produced in the form of an ellipse on the bisector.</p>
	<p>A limited heart rate variability leads to a concentration of the point cloud</p>
	<p>Rhythm disturbances and artefacts typically form outside the elliptical point clouds. Therefore, we also use this diagram as a graphical filter for artefact detection and cleaning.</p>

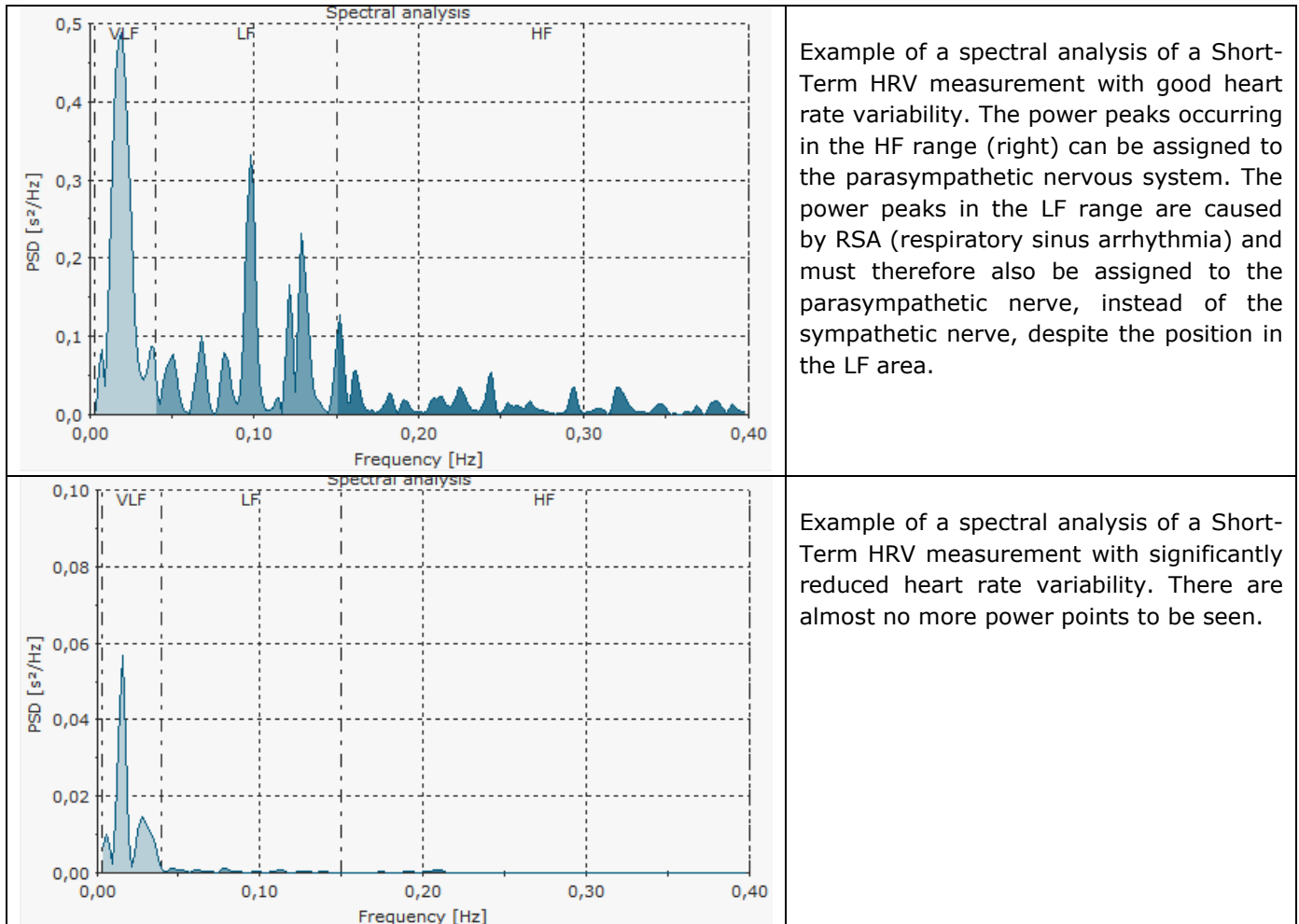
Histogram

A histogram is a graphical representation of the frequency distribution of cardinal scaled features. It requires the classification of the data into classes. Rectangles that are directly adjacent to one another are drawn from the width of the respective class whose surface contents are the class frequencies. The heartbeats occurring in the measurement are distributed to the individual classes. The height of each rectangle then represents the number of heartbeats per class.



Spectral analysis

Spectral analysis describes the values obtained from the Fourier transformation in the signal and time series analysis. In this case, the heart rate profile of a measurement is examined with regard to occurring oscillation frequencies. The aim is to determine which branch of the VNS was involved in the regulation that took place, by determining the power values for the individual frequency bands. For this, one uses the fact that the parasympathetic can regulate faster than the sympathetic due to its physiology. All vibrations occurring in the high-frequency range (HF) can be unambiguously assigned to the parasympathetic nervous system. However, the sympathetic and parasympathetic nervous system is shared by the low-frequency region (LF). An estimation of the allocation is only possible with regard to breathing. The LF/HF quotient is therefore only very limited suitable for reproducing the balance between sympathetic and parasympathetic nervous system.



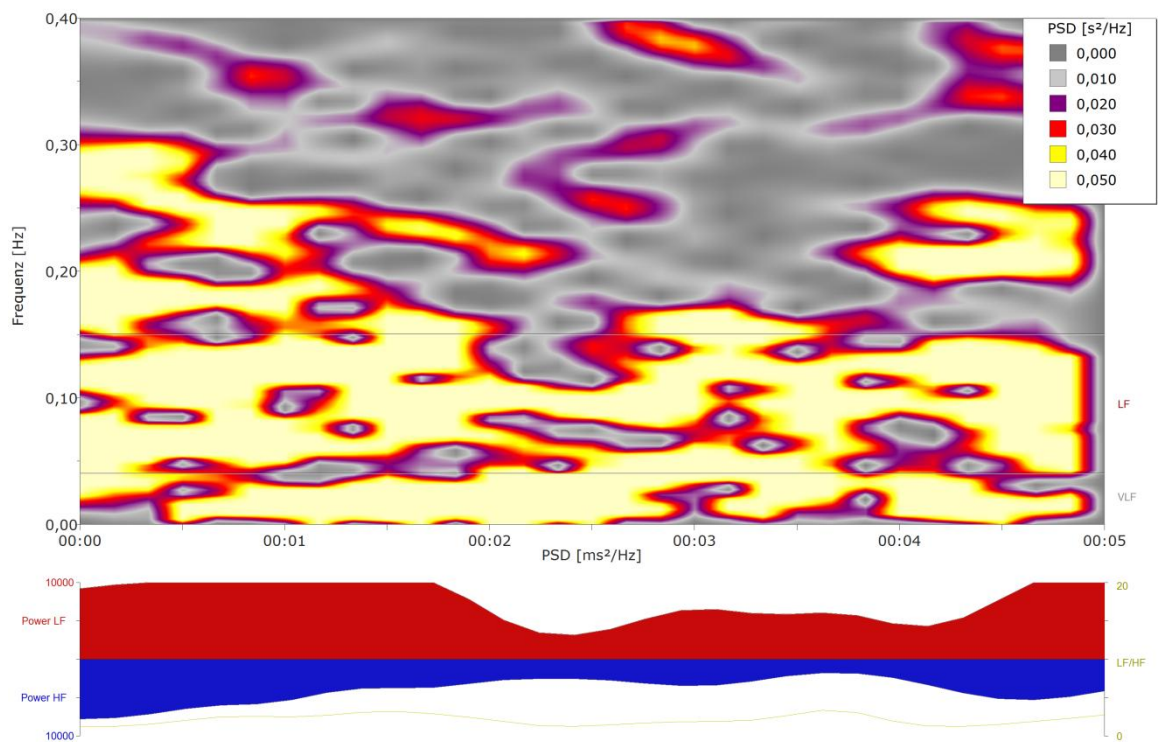
Color-FFT

Spectral analysis allows the determination of the frequency components in the heart rate curve. This can lead to the inhibition of parasympathetic and sympathetic activity within certain limits, since rapid changes in the heart rate (> 0.15 Hz) can only be triggered by parasympathetic regulation (see chapter "Parameters of heart rate variability, parameters of spectral analysis"). For longer measurements the spectral analysis can therefore be used to register the change in vegetative balance.

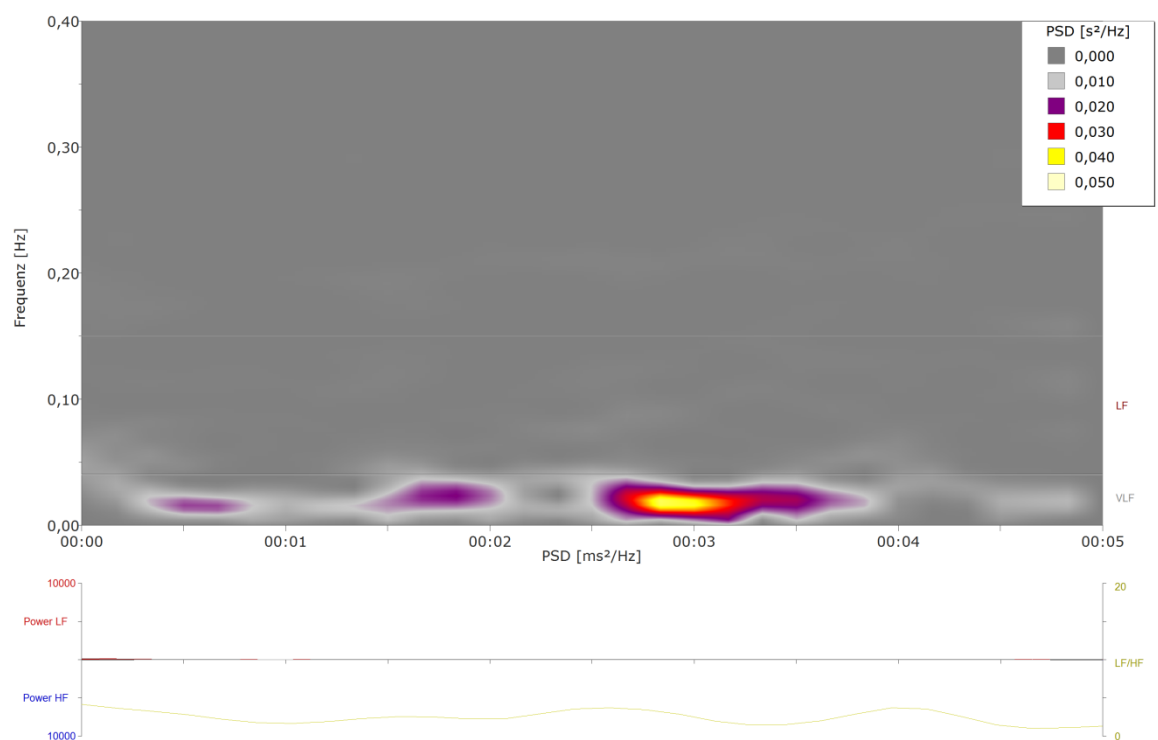
Two graphs visualize the changes in the spectral analysis during the measurement, the color FFT and the 3D FFT diagram. In the color FFT diagram, the activity in a particular frequency band is encoded by the color at a particular time.

In the lower section, the ratio LF/HF and Power LF/Power HF are displayed.

Example of a color FFT from a Short-Term HRV measurement with good HRV. The yellow bands are clearly visible as a representation of high PSD values (Power Spectral Density). High values indicate a frequent occurrence of regulation in the respective frequency range, here in the HF range as a sign of a clearly good parasympathetic function and in the LF range as a sign of a pronounced RSA and thus also a regulation from the parasympathetic nervous system.

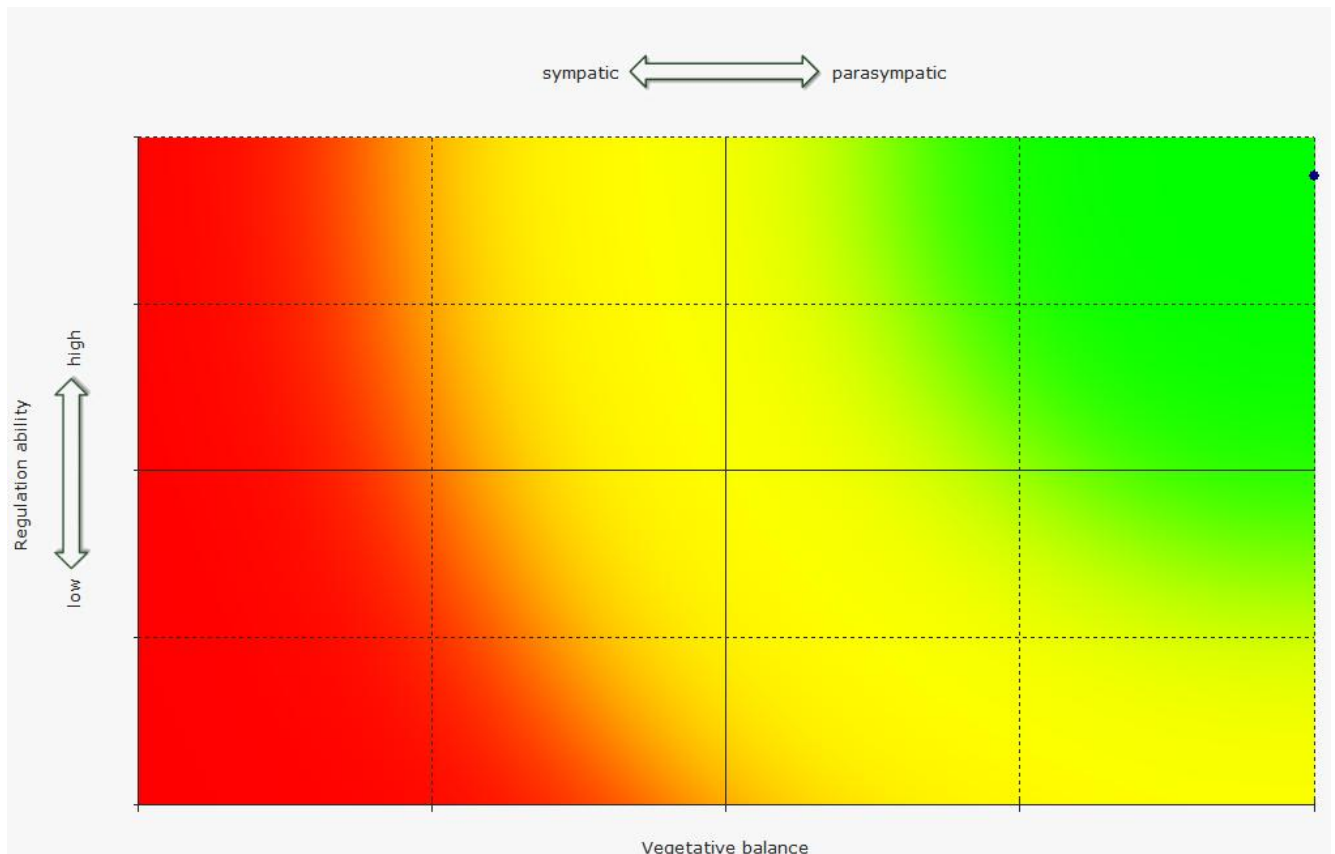


Example of a color FFT from a Short-Term HRV measurement with restricted HRV. Here, a complete absence of activity in the HF range is seen as a sign of a clear parasympathetic weakness. In the LF area only very discrete bands are visible, which also indicates a restricted regulation by the sympathetic. So overall, a very limited regulatory capacity.



ANS status

The ANS status diagram reflects the current state of the autonomic nervous system and the two opposing branches of the sympathetic and parasympathetic nervous system in two dimensions. The ratio of parasympathetic to sympathetic activity is plotted on the horizontal axis and the regulatory capacity of the vegetative nervous system on the vertical axis. Overcoming the parasympathetic is rated as "good", as is a high regulatory capacity. Therefore, in the optimal case, the blue marking is located in the right upper panel (green) and in the lower left panel (red) if the measurement results are unfavourable.



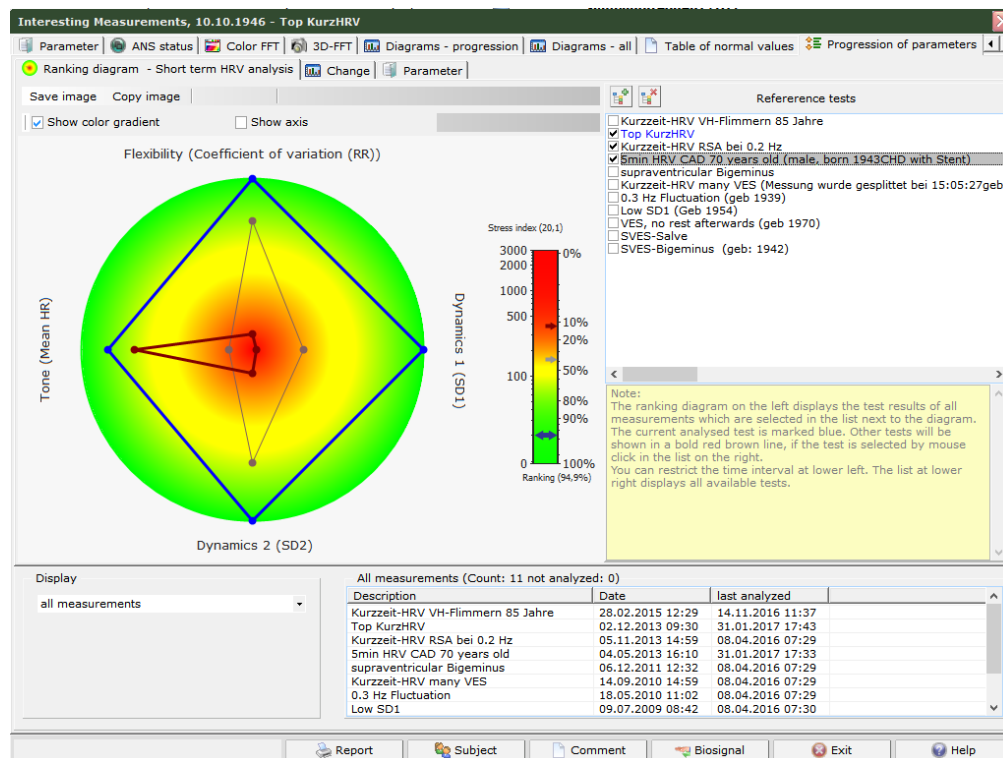
Based on heart rate variability, only a qualitative statement on an ordinal scale in the sense of "more parasympathetic than sympathetic" or "predominantly parasympathetic" can be attributed to the current state of the autonomic nervous system. An assessment in the sense of "twice as much parasympathetic as sympathetic activity" is not possible. For this reason, the diagram does not include scaling on the X axis and Y axis.

For the determination of the regulatory capacity, the age-corrected, achieved rank of the "total power" is used as the basis for both the sympathetic and the parasympathetic regulation power.

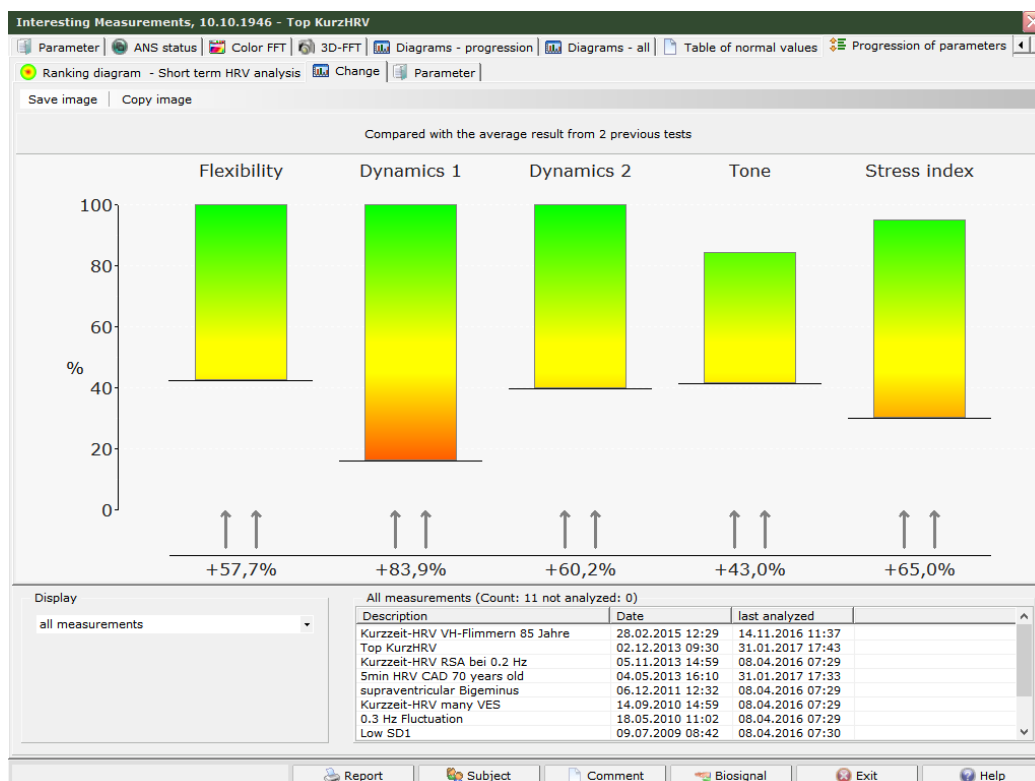
The assessment of the parasympathetic/sympathetic balance is made by means of a modified LF/HF-quotient. The LF/HF ratio is the ratio between the power in the low-frequency band (LF) of the spectrum analysis and the power in the high-frequency band (HF) and represents a measure for the vegetative balance accepted in international guidelines. However, only the HF is specific for the parasympathetic. Because only the parasympathetic can regulate in the high-frequency range due to its receptor morphology. The LF region contains both sympathetic and parasympathetic activity, which is mainly due to the influence of respiration. For this reason, the parasympathetic influence of the respiration is calculated out of the LF range in the HRV-Scanner and is attributed to the HF range. This clearly increases the separation severity of the quotient between sympathetic and parasympathetic activity.

Progression of parameters

The parameter progression shows the progress of individual parameters over time. The results of the measurements selected in the right-hand list (check mark) are displayed in the progress bar. The currently evaluated measurement is marked blue in the list, the measurement currently highlighted with the mouse appears strong in the diagram and reddish-brown. Below you can limit the time period for the display. In addition, all available measurements are displayed.



Measurement sequence as a bar chart of the individual target parameters.



List of parameters

Calculate heart rate from []

Specifies whether the heart rate is calculated from the ECG or the pulse wave

Sampling rate [Hz]

Specifies the sampling rate for the biosignal (ECG, pulse wave) on which the measurement is based.

Duration [hh:mm:ss]

Duration of the measurement

Number of heartbeats [n]

Number of heartbeats detected in the measuring range, which have not been marked or filtered as an artefact

Artefact ratio [%]

Number of heartbeats marked or filtered as artefact in relation to all heart attacks detected in the measuring range. This parameter can be used very well to give an assessment of the evaluation of an HRV measurement. An artefact ratio of 0% means no artefacts or filtered heartbeats, an artefact ratio of 100% means that all heartbeats have been marked or filtered out of the measuring range as an artefact.

Well-being [%]

(only Deep Breathing Test and Short-Term HRV)

Value from the conditional assessment before Deep Breathing Test and Short-Term HRV measurement. This value is not included in the evaluation, but primarily serves to better interpret a measurement. Measurements with a rather subjectively tense condition suggest a worse result than measurements with a subjectively relaxed state of mind.

DBT quality [%]

(only Deep Breathing Test, instead of test quality)

Criterion about the quality of an Deep Breathing Test. Essentially, the uniformity of the heart rate matching resulting from the breathing is judged.

Test quality [%]

Criterion about the quality of a measurement. The measurement quality is adversely affected by sections with missing heartbeat (e.g., too many motion artefacts, ...) and sections with irregular rhythm.

Biofeedback quality [%]

(only biofeedback, instead of test quality)

Criterion about the quality of a biofeedback session on the basis of the measurement quality.

Subject age [years]

Age of the subject at the time of the measurement (calculation from the date of birth in the subject administration)

Subject height [cm]

Body size of the subject at the time of the measurement (transfer of the body size from the subjects management at the time of the measurement)

Subject weight [kg] (initial)

Weight of the subject at the time of the measurement (transfer of the weight value from the subjects management at the time of the measurement)

Subject sex

Sex at the time of the measurement (assumption of the sex from the subjects management at the time of the measurement)

Examiner

Which examiner did this measurement

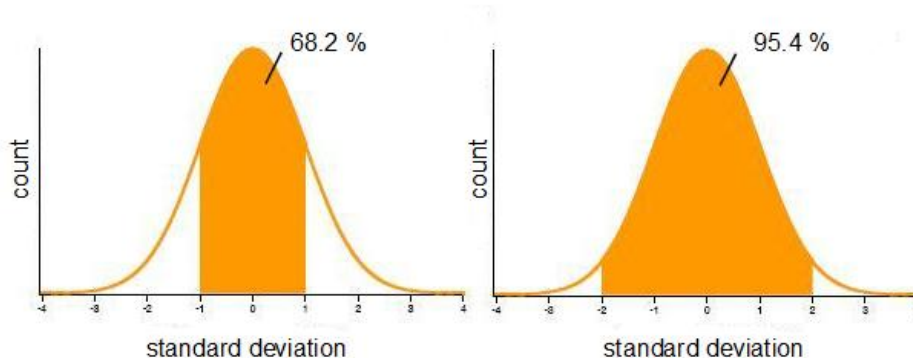
Mean HR [1/min.]

Average heart rate during the measurement.

Standard deviation (St.Dev.) [ms]**Coefficient of variation (HR) [%]**

These parameters are derived from descriptive statistics. They express the width of the distribution of individual values around the mean value. It seems natural to use statistics as descriptors for HRV, because HRV itself can be interpreted as a statistical phenomenon: the individual heart rate values within a measurement vary around a mean heart rate, such that larger deviations are less frequent than values closer to the mean.

A classical distribution with these characteristics is the Gaussian (or "normal") curve:



In a Gaussian distribution, 68.2% of all heart rate values will fall within in the area corresponding to the first SD around the mean, and 95.4 % of the values will fall within 2 SDs of the mean. The coefficient of variation (cv) combines SD and mean into a single value. The cv is computed as follows:

Standard deviation

$$\frac{\text{Standard deviation}}{\text{Mean}} \times 100 = \text{cv}$$

Mean

The cv is expressed as a percentage. A cv of 10%, for instance, indicates that 68.2 % of the heartbeats are within a range of +/- 10% of the mean heart rate.

So: the higher the standard deviation or the VK, the greater the heart rate variability.

Mean RR interval [ms]

Analogous to the mean heart rate, the mean RR distance indicates the average RR interval of all heart attacks of the measurement.

SDNN [ms]

Standard deviation of the RR intervals. Analogous to the standard deviation of the heart frequencies, these statistical measures can also be expected over the RR intervals. The SDNN is a frequency - independent indicator of the overall variability (high SDNN - high HRV, low SDNN - low HRV)

PNN50 [%]

Percentage of successive RR intervals that deviate more than 50 milliseconds. A high pNN50 value means high spontaneous changes in heart rate

PNN20 [%]

Percentage of consecutive RR intervals that deviate more than 20 milliseconds.

Coefficient of variation (RR)

Similar to the coefficient of variation calculated from the heart frequencies, these statistical measures can also be calculated over the RR intervals.

RMSSD [ms]

(root mean square of successive differences - Meaning: root from the mean value of the squared differences of the RR intervals of successive heartbeats) The RMSSD is mathematically somewhat complicated, but it describes a simple fact: It expresses how much the heart rate changes from one heartbeat to the next.

$$RMSSD = \sqrt{\frac{1}{N} \times \sum_{i=1}^N (RR_{i+1} - RR_i)^2}$$

Artefacts are characterized by strong jumps of heart rate. In artefacts, therefore, the heart rate changes from one heart to the next. For this reason, the RMSSD is very sensitive to artefacts. A high RMSSD with a comparatively low standard deviation or a low coefficient of variation should be the reason to test the measurement for artefacts.

SD1 [ms]

SD2 [ms]

SD1 and SD2 describe the scattering of the heartbeats in the Poincaré diagram. SD1 expresses the width of the point clouds and is more sensitive to fast, higher frequency changes in the heart rate whereas SD2 describes the length of the point cloud and rather quantifies the long term HRV.

SD2/SD1 quotient

The SD2SD1 quotient is the ratio of the already known parameters SD2 to SD1, which can be calculated from the Poincare plot. SD2 reflects slow heart rate changes, whereas SD1 quantifies the rapid heart rate change from beat to beat. The ratio of the two parameters therefore expresses the ratio of slow changes in the heart rate as compared to rapid fluctuations in the heart rate.

The SD2/SD1 quotient is comparable to the LF/HF quotient, which is commonly used to quantify the autonomous equilibrium. One uses the characteristic of the parasympathetic to be able to change the heart rate relatively quickly - in contrast to the rather inert sympathetic. Vibrations in the high frequency band (HF) are therefore caused mainly by the parasympathetic activity, the sympathetic plays practically no role here. However, this clear separation between sympathetic and parasympathetic activity cannot be performed for the low frequency band (LF) because both branches of the autonomic nervous system (ANS) can cause slow fluctuations in the heart rate.

Due to the lack of discrimination in the LF range, the LF/HF quotient is at best a rough measure for the autonomous equilibrium. In addition, there is a second limitation on the practical usability resulting from its sensitivity to the influence of breathing. Breathing leads to sinusoidal oscillations of heart rate (respiratory sinus arrhythmia, RSA). Depending on the respiratory rate, the RSA is either in the LF band or in the HF band. The limit between HF and LF band is achieved with a breathing rate of 9 breaths. Higher breathing frequencies contribute to the HF band, lower breathing frequencies increase the LF performance. However, the RSA is always mediated by the parasympathetic system, independent of the respiratory rate. This causes a high LF/HF quotient in the presence of a high RSA and respiratory frequencies below 9 breaths per minute, which is often misinterpreted as overcoming the sympathetic. Small changes in respiratory rate, e.g. from 8 to 10 breaths per minute, can completely reverse the LF/HF quotients. Therefore, the LF/HF quotient is not a good measure to express the ratio of slow to fast heart rate changes.

Instead, we propose to use the SD2/SD1 ratio instead of the LF/HF quotient, since the SD2/SD1 quotient does not have frequency bands and has a continuous curve. (see figure 1).

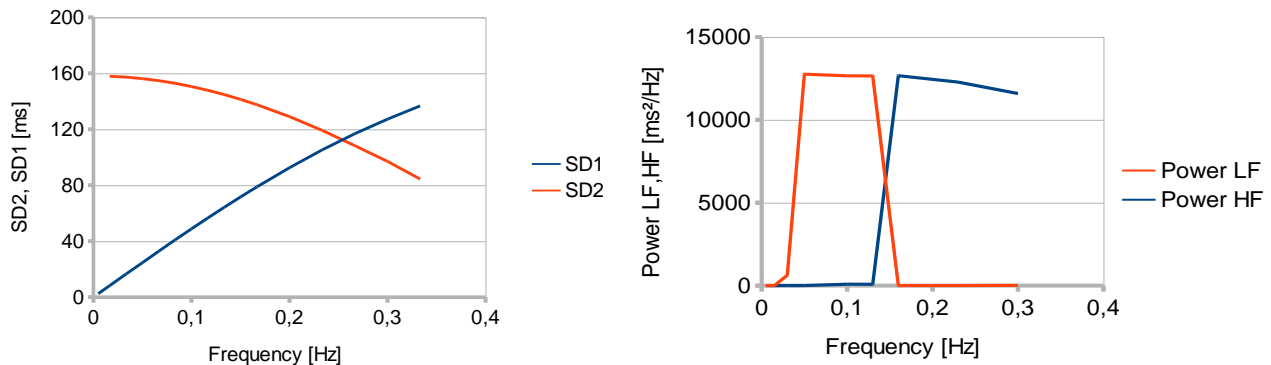


Figure 1

Individual heart rate oscillations of different frequencies from 0.005 Hz to 0.33 Hz, each with a constant amplitude of 20 beats / min, were analyzed one after the other in a computer simulation. The resulting values for SD2 and SD1 are shown (see left diagram). The right diagram shows the corresponding curves for the Power HF and Power LF.

As expected, SD1 decreases with increasing frequency while SD2 decreases. In contrast, the power values change with increasing frequency only when the oscillation changes the frequency band. The power values behave more like a binary on/off switch, but they are not able to display small changes in the dynamics.

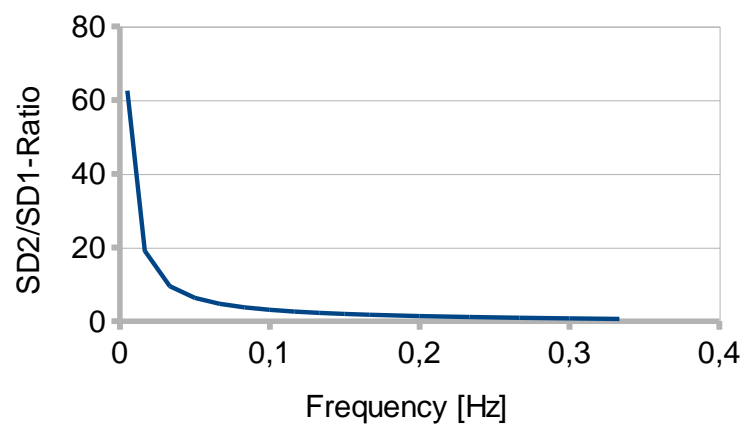


Figure 2 Course of the SD2/SD1 quotient for the corresponding SD values of Figure 1.

Normalized SD2/SD1 quotient [σ]

The calculation of the SD2/SD1 quotient leads almost automatically to the question, what is a "normal" SD2/SD1 quotient and what is not. We therefore analyzed the distribution of the SD2/SD1 ratio in numerous Short-Term HRV measurements obtained in two different clinical trials. The first study was a standard value study, in the second study many people were subjected to a Short-Term HRV measurement. In this study, there were no strict exclusion criteria (cross-sectional study). In the first study ($n = 204$), an average SD2/SD1 ratio of 2.9 and the 95% interval of 1.37 to 5.97 resulted in a second study ($n = 639$) Similar distribution of the SD2/SD1 quotient: mean value: 3.1; 95% interval of 1.53 to 6.4.

For normalization, a Gaussian distribution was obtained by calculating the natural logarithm of the SD2/SD1 quotients (Kolmogorov Smirnov test > 0.2 , Lilliefors > 0.2). The normalized SD2/SD1 quotient is then obtained as the difference of an SD2/SD1 quotient from the mean value of the Gaussian distribution, expressed as a multiple of the standard deviation.

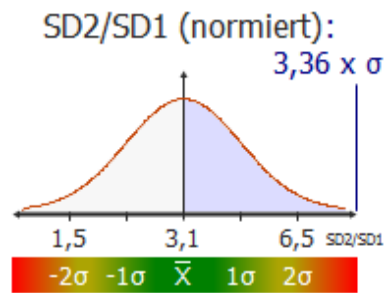


Figure 3

Gaussian distribution of the SD2/SD1 ratios of the two studies ($n = 843$). A normalized SD2/SD1 value of, for example, 2σ means accordingly an SD2/SD1 quotient, which is two standard deviations to the right of the mean value. Because of the Gaussian distribution, only 2.3% of the people had an even higher SD / SD1 value.

Related to other HRV parameters

HRV parameters are usually highly correlated among each other. Thus, the correlation coefficient r in the Short-Term HRV measurements taken between Power HF and SD1 is 0.93. The relationship between Power LF and SD2 is also high with an r of 0.84. Other "classical" HRV parameters such as pnn50, SDNN and stress index are highly correlated among each other. Interestingly this is not so for the SD2/SD1 ratio - whether normalized or not. The correlation with the "classical" HRV parameters is comparatively low. If this were different and a high agreement would be found with one of the other usual HRV parameters, the additional benefit of the SD2/SD1 ratio would be low, the information would already be coded in another parameter. However, since this is not the case, the question arises whether information is contained in the SD2/SD1 quotient which is not reflected in the classical HRV parameters.

This seems to be because comparatively high correlations with two other clinically relevant HRV parameters are more likely to be attributed to the nonlinear HRV analysis: the α_1 value of Detrended Fluctuation Analysis (DFA) and the auto-correlation coefficient (ICC). The correlation of the standard SD2/SD1 ratio with DFA- α_1 was 0.71 in the examined measurements and even 0.93 with the autocorrelation coefficient ICC. The good correlation with DFA- α_1 has already been confirmed by third parties in a recent study¹.

There are a number of studies that demonstrate that a reduced α_1 -DFA is associated with an increased mortality risk of ^{2,3,4,5,6}. In a study, the SD1/SD2 ratio, which is the reciprocal of our SD2/SD1 ratio, had the strongest association with mortality after heart attack ². The higher the SD1/SD2 quotient (= the lower the SD2/SD1 quotient), the higher the mortality risk. In another recent study of the relationship between coronary heart disease and HRV, it was interesting to see the opposite relationship between the SD2/SD1 ratio and the coronary heart disease. ⁷. The higher the SD2/SD1 ratio, the stronger the damage of the coronary arteries.

These seemingly contradictory results can be explained by the underlying physiology:

Physiological significance

High SD2/SD1 ratios show a dominance of slow heart rate fluctuations. This can result from an over activity of the sympathetic system and / or a weakness of the parasympathetic branch of the ANS, which can both adversely affect health. The higher the normalized SD2/SD1 quotient, the more unlikely it will reflect good parasympathetic activity. A lack of parasympathetic activity is correlated with the onset of inflammatory mediators in the blood, e.g. CRP, which is associated with inflammatory processes in the coronary arteries and the development of coronary heart disease.

In contrast, lower SD2/SD1 ratios indicate a sufficient occurrence of fast heart rate oscillations. Nevertheless, the low SD2/SD1 ratios were associated with higher mortality in several studies. This was due to the fact that such cases were no longer a "healthy" sinus rhythm, but either rhythmic disturbances or an "erratic" sinus rhythm, which is a prognostically rather unfavourable sign ⁶.

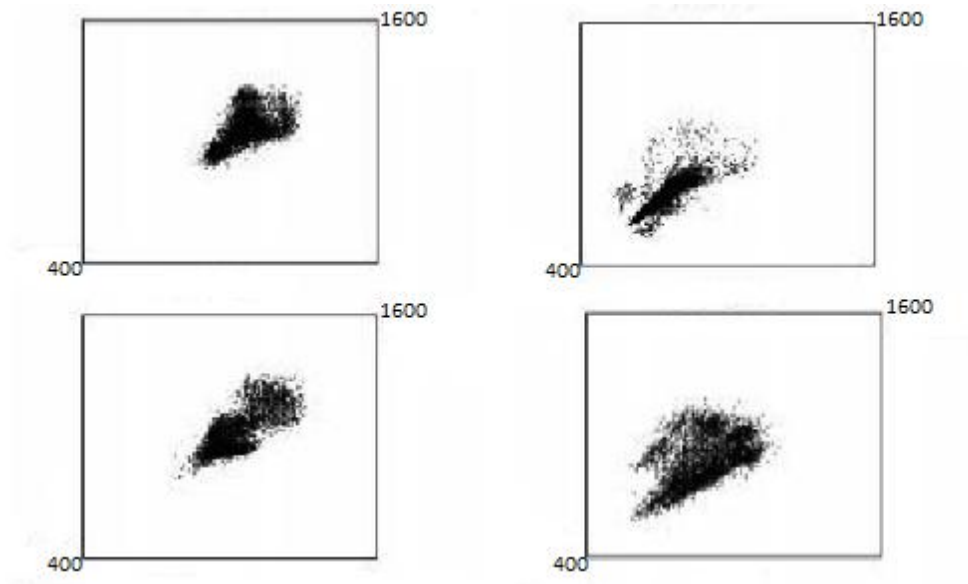


Figure 4 - Poincare plots of erratic sinus rhythms

Conclusion

Thus, an excessively high SD2/SD1 ratio would be unfavourable.



We therefore propose the following approach to interpretation:

Normalized SD2/SD1 quotient	Interpretation
< -1 σ	<p>Noticeable low result</p> <p>In the first step, check for artefacts and irregular heart beats and remove them if necessary.</p> <p>In the second step, check whether there is a sinus rhythm (atrial fibrillation?). No meaningful HRV analysis can be performed without sinus rhythm.</p> <p>Age and medical history must be considered. Higher age and evidence of coronary heart disease or infarction suggest a more erratic sinus rhythm. In young athletes, very low SD2/SD1 ratios are indicative of a high dynamic regulation capacity of the parasympathetic nervous system.</p> <p>If a suspicious sinus rhythm is suspected, a 24 hour HRV measurement is recommended.</p>
-1 σ to 1 σ	Normal findings
> 1 σ	<p>Noticeable high result</p> <p>Significant overcoming of slow heart rate changes.</p> <p>Usually other signs of parasympathetic dysfunction are present (low SD1, low power HF, high stress index)</p>

The corresponding literature for the SD2/SD1 parameter can be found in the appendix.

Stress index [Pts.]

The stress index is calculated based on Prof. Baevsky, who developed and validated this parameter within the framework of Russian space medicine. The stress index is becoming increasingly popular because it is sensitive to shifts in the vegetative balance between sympathetic and parasympathetic nervous system. It ultimately represents a mathematical description of the histogram:

$$\text{Stressindex} = \frac{A_{mo}}{2 \times M_o \times M_{xDMn}}$$

M_o = modal value, most frequent value of the RR interval; A_{mo} = number of RR intervals corresponding to the modal value as a percentage of the total number of all measured values; M_{xDMn} = variability width, difference of the maximum and minimum RR intervals.

Because of its sensitivity, the stress index is a good measure to register changes within a subject over time. However, like all other HRV parameters, it is strongly influenced by the overall state of neurovegetative regulation. That is, an organically induced restriction of HRV (e.g., as a complication of long-term diabetes) is indicated by a high to very high stress index without stress loading.

HF-Band [Hz]

LF-Band [Hz]

VLF-Band [Hz]

Definition of the ranges for the separation of spectral analysis into different bands (High frequency, Low frequency, Very low frequency)

Power HF-band [ms^2]

High Frequency Power, Power density spectrum in the frequency range of e.g. 0.15 to 0.40 Hz; Shows exclusively the parasympathetic part

Power LF-band [ms^2]

Low Frequency Power, Power density spectrum in the frequency range of e.g. 0.15 to 0.40 Hz; Both the sympathetic and the parasympathetic are involved, with the sympathetic being predominant.

Power VLF-band [ms^2]

Very Low Frequency Power, Power density spectrum in the frequency range of e.g. 0.15 to 0.40 Hz; Other central nervous sources of cardiac regulation are visible in the VLF band

Power total [ms^2]

The total power quantifies the total power over all frequency bands

rel. Power HF-band [%]

rel. Power LF-band [%]

rel. Power VLF-band [%]

The relative power of a frequency band indicates the percentage of the power of the frequency band as a percentage of the total power.

LF/HF ratio

The so-called LF / HF quotient indicates the ratio of the power in the LF band to the power in the HF band. It is often referred to as an expression of the vegetative balance of parasympathetic and sympathetic nervous system. This is, however, only partially true. Although the HF range is reliably assigned to the parasympathetic, the LF range contains both sympathetic and parasympathetically mediated regulation of heart rate. If, for example, pronounced respiratory sinus arrhythmia is present in slow and deep breathing, a very large LF / HF quotient is obtained, which, however, does not indicate strong sympathetic activity, but is an expression of well-functioning parasympathetic regulation.

Rhythmisation degree [°]

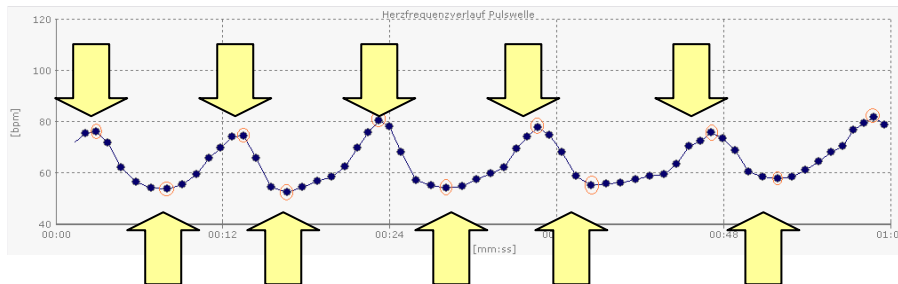
The degree of rhythmization quantifies "quality" and "quantity" of respiratory sinus arrhythmia. "Quantity" means the size (amplitude) of the resp. Sinus arrhythmia, "quality" expresses whether, in addition to the resp. Sinus arrhythmia, other regulatory processes in the heart rate are visible. Especially in the case of HRV biofeedback, the degree of rhythmicity plays an important role because a high degree of rhythmization (large resp. sinus arrhythmia, small other control processes) is here specifically trained.

E-I [1/min.]

E/I []

(Expiration-/Inspiration difference or quotient) - only Deep Breathing Test

The calculation of the E-I is the "classical" evaluation of a deep breathing test, as it is evaluated, for example, in hospitals that have an autonomous function laboratory. E-I and E / I are direct measures of respiratory sinus arrhythmia. The HRV-Scanner software calculates the highest and the lowest heart rate for each individual breathing cycle (see picture).



The E-I or E/I can now be calculated from the highest and lowest heart rate of each respiratory cycle. Because of the calculation basis using median values, E-I and E/I are relatively robust against artefacts. In the interpretation of the E-I, it should be noted that subjects with a very low mean heart rate (≤ 50 / min) have a low E-I as a subject with a normal or higher heart rate. The reason for this is the AV node (atrioventricular nodes, secondary pacemakers of the heart adjacent to the sinus node as a primary pacemaker), which limits the frequency drop down ($<40-50$ / min).

MCR []

(Mean Circular Resultant) - only Deep Breathing Test

The MCR represents a vector whose magnitude correlates well with the magnitude of respiratory sinus arrhythmia and is relatively insensitive to outliers and artefacts.

$$MCR = \sqrt{\left[\sum_{i=1}^n \cos\left(\frac{2\pi T_i}{\lambda}\right) \right]^2 + \left[\sum_{i=1}^n \sin\left(\frac{2\pi T_i}{\lambda}\right) \right]^2}$$

λ = cycle length; T_1, T_2, \dots, T_n : time of the single heartbeats

(See also: Weinberg CR and Pfeifer MA, 1984, An improved method for measuring heart rate variability: assessment of cardiac autonomic function Biometrics 40: 855-61)

Ewing 30:15 value []

synonym. 30/15 ratio, 30/15 ratio (only lying / standing measurements)

The Ewing parameters quantify the change in heart rate after standing up. According to Ewing, the RR 15 indicates the RR interval of the 15th heartbeat after rising and the RR 30 the RR interval of the 30th heartbeat after rising. Since there are inter-individual differences in the response to standing up, the longest RR interval of the beats 5 to 25 and the shortest RR interval of the beats 20 to 40 are related in the HRV-Scanner. This has proven itself in practice, see Ziegler et al.

(Ziegler D., Laux G., Dannehl K., Spüler M., Mühlen H., Mayer P., Gries F.A., Assessment of Cardiovascular Autonomic Function: Age-related Normal Ranges and Reproducibility of Spectral Analysis, vector Analysis, and Standard Tests of Heart Rate Variation and Blood Pressure Responses, Diabetic Medicine, 1992, 9:166-175)

Biological HRV age [years]

(only Deep Breathing Test and Short-Term HRV)

The HRV is a strongly age-dependent variable. The older we become, the lower the HRV is usually. However, this is (in certain limits) a reversible effect. It can therefore be of interest to know the age of the HRV. To determine the biological HRV age, the age at which exactly 50% of the healthy subjects have better and 50% worse HRV values in the Deep Breathing Test is calculated. For the calculation in the Deep Breathing Test, E-I, E/I, MCR and RMSSD are used, for the Short-Term HRV SD1, SD2, Power HF, Power LF, Total Power and Stress index.

Valsalva-Ratio

(only Valsalva manoeuvre)

Quotient of the longest RR interval after the end of the press manoeuvre (reflexive bradycardia) and the shortest RR interval during the press manoeuvre.

Alpha 1 []

(detrended fluctuation analysis)

Calculation

In the theory, the "detrended fluctuation analysis" (DFA) quantifies the fractal properties (self-similarity) of a heart rate curve. For the calculation, the RR intervals are integrated and subdivided into sections of defined number of n RR intervals, where n increases with each run. In each section, the trend is removed and the resulting fluctuation of the RR intervals is calculated. The average fluctuation $F(n)$ is determined for all section variables n .

The resulting slope of the regression line in the $\log(F(n))$ to $\log(n)$ representation corresponds to the scalene exponent α . If the slope is calculated over short section sizes n (e.g., 4-16 heart rate per section), the resulting scale exponent expresses α short-term correlations (α_1 and DFA1, respectively). The slope over larger section sizes (e.g., n : 16-64) corresponds to correlations over a longer period of time (α_2 and DFA2, respectively). An α_1 of 0.5 indicates a completely random heart rate curve. A value of 1.5, on the other hand, would be a strongly autocorrected signal.

Physiological significance

There are several studies showing a good prognostic value of α_1 and α_2 in the 24-ECG, e.g. According to myocardial infarction (α_1) or mortality in the elderly (α_2).

Correlation to other HRV parameters

DFA1 is highly correlated with the parameter $LF / (LF + HF)$ and the $SD2 / SD1$ ratio. This relationship has already been described in the literature and is confirmed by BioSign in its own investigations. In a BioSign study with approximately 500 subjects, the correlation of α_1 and the $SD2 / SD1$ ratio was 0.71 and the $LF / (LF + HF)$ ratio was 0.72.

Thus, similar to the $SD2 / SD1$ ratio, DFA1 is a time domain equivalent of the spectral indices and therefore cannot distinguish linear from non-linear correlations. The most obvious difference between the DFA and the spectral analysis is that the DFA measures the examination sections in heart attacks, in contrast to the spectral analysis, which analyzes defined time sections.

Clinical benefit

Particularly in the case of short-term analyzes, the DFA must be interpreted with caution. The analyzes of BioSign show a strong correlation with the influence of respiration for DFA1. In the study already mentioned in 500 subjects, the correlation with the influence of breathing (cross-correlation of breathing signal and heart rate curve) was 0.53. A regression analysis with the independent variables $SD2 / SD1$, $LF / (LF + HF)$ and the influence of the respiration showed a correlation of 0.88.

Thus, it seems unlikely that the DFA can add significant additional information beyond the existing parameters of the time domain and frequency domain in the case of short-term HRV analyzes. The practical benefit of the DFA in the short-term HRV is also limited by the strong spread of the values. In the above study, the mean DFA1 was 1.03 and the standard deviation was 0.23. Due to the strong spread of the DFA1 values in the short-term HRV also in the normal population, no meaningful standard value limits can be specified.

Respiration parameters

(only Short-Term HRV)

Breathing is the primary trigger for the HRV at rest. It is therefore extremely helpful to take into account in evaluating a Short-Term HRV. A poor test result in the Short-Term HRV is not necessarily the expression of a parasympathetic regulatory disorder, but the subject may simply have breathed far too quickly and too flatly (e.g., high stress level). This can lead to seemingly contradictory findings in the Deep Breathing Test, where a good result is often obtained. It is therefore recommended to take a look at the breathing during the evaluation.

Impact breathing [%]

Influence of breathing on the change in heart rate. The larger the percentage, the more pronounced the respiratory sinus arrhythmia and the more relaxed is the measured person.

Respiratory rate [1min.]

Average breathing rate in the selected measuring section. High respiratory frequencies usually lead to a lower HRV. It is therefore advisable to check the respiratory frequency at low HRV values. However, even very slow breathing frequencies (<6 breaths per minute) can lead to low SD1 or RMSSD values because the parasympathetic is also slow to control with slow breathing.

Respiration stress[]

Estimation of stress from breathing. Similar to the stress index in the HRV, the respiratory stress value increases steeply (exponentially) if the respiratory rate is too high. Respiration stress and respiratory rate basically express the same thing (increase of the breathing frequency) and are therefore evaluated similarly in the corresponding normal value graphs. Note: strongly different assessments of respiratory rate and respiratory rate may occur when breathing is measured via EDR (ECG derivative respiration) and the EDR signal cannot be derived cleanly. In this case, the respiration parameters should not be included in the assessment.

Breathing variability []

Variability of breathing during measurement. A calm even breathing is characteristic of a relaxed state. High variability values can, for example, indicate mental stresses ("head kino").

Pulse wave latency [ms]

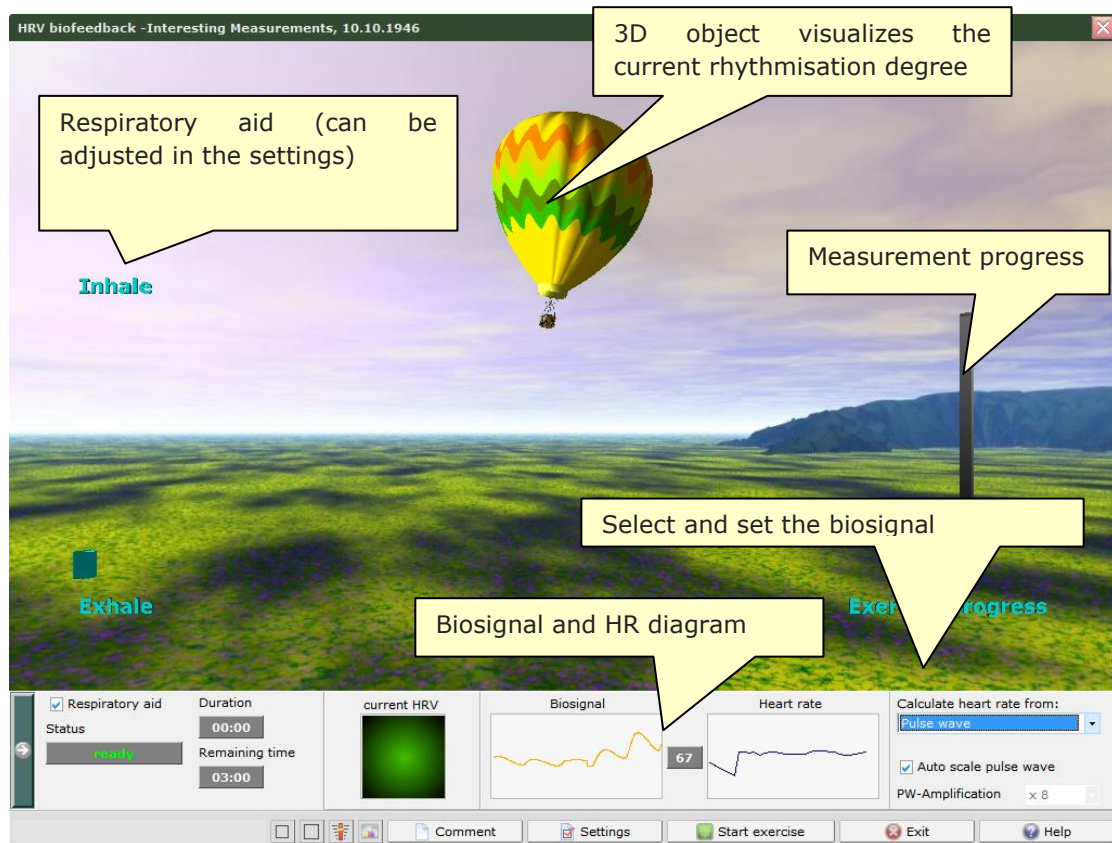
The pulse wave latency or pulse transit time (PTT) is a cardiovascular measurement value. It describes the time that a pulse wave requires to travel a certain distance in the vascular system. By measuring the pulse wave time, conclusions can be drawn about important vital parameters such as blood pressure and elasticity of the vessels. In the HRV-Scanner, the PTT is calculated from the temporal distance of the R-wave from the ECG and the pulse wave (e.g., ear clip at the ear).

HRV biofeedback

There are three modes of HRV biofeedback available in the HRV-Scanner:

HRV biofeedback

The biofeedback window shows in the basic setting a scene that has a relaxing effect on the subjects (different landscapes are available in the settings) and visualizes the calculated biofeedback parameters via an object (balloon, butterfly, ...). A pleasant background music and spoken instructions helps the subject to relax quickly and effectively.



Biofeedback window showing a scene with a balloon

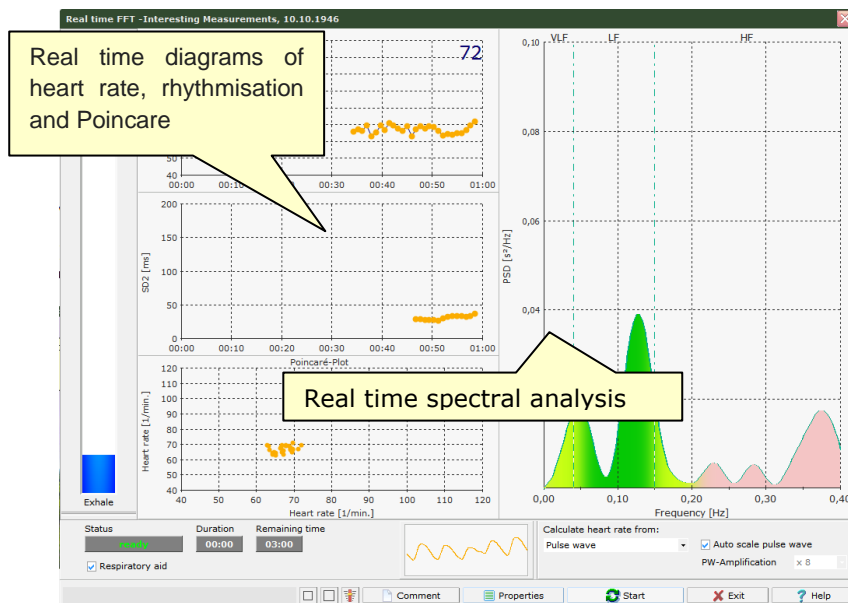
In the left part of the biofeedback window is the respiratory aid, which indicates the rhythm of the breathing. You can customize the breathing rhythm in the settings or hide it completely. The bar on the right represents the progress of the biofeedback exercise (the duration of the exercise can also be adjusted in the settings).

In the lower window there are further settings: the display for the current HRV, the biosignal, the current heart rate and the settings for the biosignal (gain, sensitivity) and heart rate detection.

The remaining measurement time and the elapsed time are shown in the status field. After the measurement time has expired, you will receive a message about the successful recording of the measurement. Close the biofeedback window. The measurement data is packed into an archive and an entry for the new measurement appears in the "Test and analysis" window.

Online spectral analysis (Real time FFT)

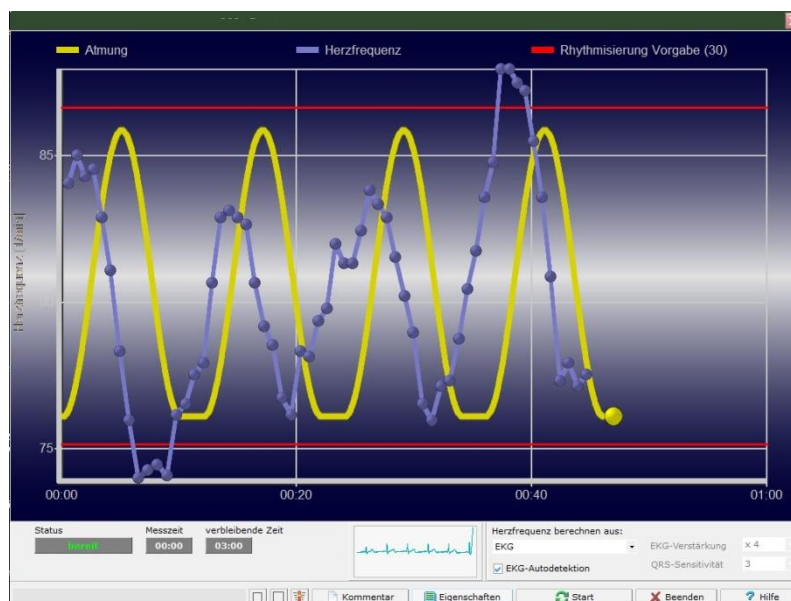
The online spectrum is similar to HRV biofeedback. Instead of a object, real time diagrams represent the current HRV. There is a online spectral analysis, a heart rate and Poincaré diagram and the current degree of rhythm.



Online spectrum window

Rhythmisation

The rhythmisation is similar to the HRV biofeedback. The displayed respiratory curve (breathing pattern) and the heart rate progress should be synchronized.



Rhythmization - the breathing curve and heart rate should be synchronized

Fundamentals of HRV Biofeedback

From chaos to order

A variable heart rhythm is better than a too rigid rhythm. However, it is still much better to convert the disordered "chaotic" heart rate variability into an ordered, "rhythmized" heart rate variability (see figure).



"chaotic"



"rhythmized"

Rhythming occurs when the breathing and the heart rate are in a state of relaxation (coherence). With each inhalation, the heart rate increases, with each exhalation it falls off. When the state of the rhythm is reached, it has been possible to activate the "internal brake", the parasympathetic nerve. In many relaxation techniques (such as yoga, autogenous training), this coupling between breathing and heartbeat takes place in the state of relaxation. Using the HRV biofeedback, you can now train this process in a targeted way and get information on how well breathing and heartbeat are rhythmically.

How do we achieve a state of coherence or rhythm?

Breathing is the key to coherence

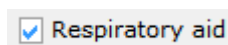


Respiratory aid

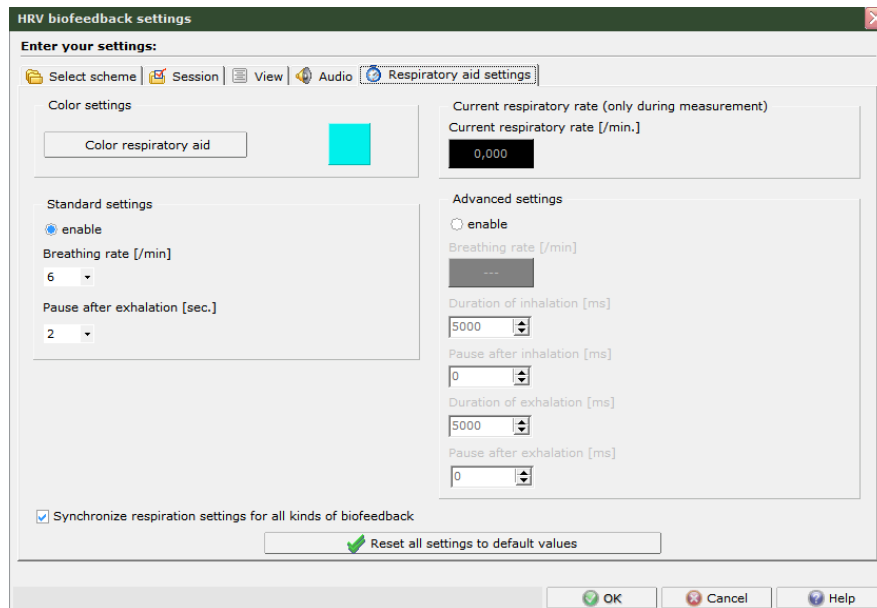
As it is said, coherence is the consistency of breathing and heartbeat. Proper breathing is therefore the central component of any successful HRV biofeedback. To assist in the proper breathing, the HRV-Scanner has a breathing aid:

The breathing aid is located on the left side of the screen. You see a colored bar, which moves rhythmically up and down. It is important to breathe in the rhythm of the beam. Inhale when the beam goes up, exhale when the beam moves down. The best breathing rate is 6 breaths per minute. At this breathing rate, HRV biofeedback is most effective.

If the subject does not get along with this breathing rhythm and the respiratory aid is disturbing, you can also hide it. To do this, deactivate the appropriate checkbox:



You can change and adjust the settings for the breath (e.g. frequency) in the "Settings" of the HRV biofeedback:

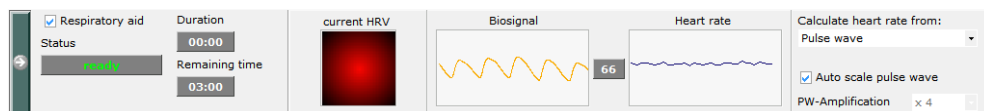


As you learn, breathing and heartbeat are rhythmic

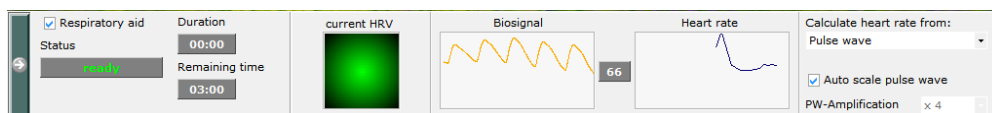
Focus your attention on the color chart at the bottom left:



The color chart shows you the current rhythm level (HRV).



If the color chart is red, the current rhythm level is low, respiration and heartbeat are separated. The heart rate runs irregularly and does not show the regular up and down of the breathing.



Very different here. You can already see the heart rate of how well its course is linked to breathing. Breathing and heartbeat are rhythmicized. The parasympathetic, the "internal brake", is now active.

How to improve coherence through biofeedback

The color chart, the central object (balloon, butterfly, ...) the graphs in the online spectrum or the course of the curves in the rhythm are a very important part of the coherence training. We use them, as it were, as a feedback, in order to improve the degree of rhythmization. This technique is also called biofeedback. Biofeedback is a method that is used successfully in many areas of medicine to influence the body's involuntary processes. We use biofeedback within the HRV biofeedback to activate the "inner brake" even more.

What to do if coherence is always low?

For example, the color chart is predominantly red, no matter how much the user tries to breathe properly while performing the biofeedback?

First check the pulse signal. Are you sure the pulse signal is OK?

If so, please note the following: The ability to achieve coherence varies from person to person. With age, for example, coherence is reduced. Likewise, hypertension, overweight, heart disease, chronic stress and various metabolic disorders lead to a loss of coherence. It is therefore advisable to measure the personal ability to coherence and compare it with others. This allows you to estimate whether the subject has low, normal, or even high coherence in comparison with others.

If personal coherence is low, the subject should not be discouraged. This is the best reason to do regular HRV Biofeedback. For this, however, you should adjust the HRV biofeedback to the personal level of the subject in the settings.

Click on the "Settings" button to access the settings window. Got to "Session". Set the default value for the Rhythmisation target degree value to a lower level and click OK. Now it should be easier for the subject to color the color chart. This makes biofeedback more effective.

What does the balloon mean in the centre of the screen?

The HRV biofeedback is designed in such a way that it can be completed in a certain, preset time. The basic setting is three minutes. To set a different duration, enter the settings window and set the duration to your choice.

In the given period, a high degree of rhythmization should be maintained. The better this is achieved, the better the exercise is completed in the set duration. The HRV-Scanner calculates the current level of the rhythm and displays it by means of the object in the screen centre.

For the individual objects, the following changes occur during the biofeedback as a function of the achieved rhythm:

Object	low rhythmization	high rhythmization
Balloon	balloon sinks	balloon rises
Butterfly	butterfly sinks, flutters restlessly	butterfly rises, flies calmly
Sphere	rotates fast	rotates little or not at all

How often and how long should you practice HRV Biofeedback?

"There is still no" scientifically verified "data on the" correct "exercise period. From the practical experience, however, one can deduce that the "correct" exercise period - that is, the probability that a positive effect is felt - is probably very different. However, since you hardly know how much a person is doing well or how much exercise you need, you should start with about three to five minutes HRV Biofeedback two to three times a day. If the subject is doing well, he can also practice 10 minutes two to three times a day.

Important settings in HRV Biofeedback

In addition to the settings for landscape, music, language, etc., there are a few settings which must be adapted individually to the subjects. These are:

Breathing rhythm

Set the breathing pattern so that the practitioner feels that breathing is relaxing. People with stress problems often have a fast and shallow breathing. Here it is not very helpful to press the practitioner into a very slow breathing. The frequency of breathing should be gradually adjusted. The goal is breathing by 6/min.

Exercise duration

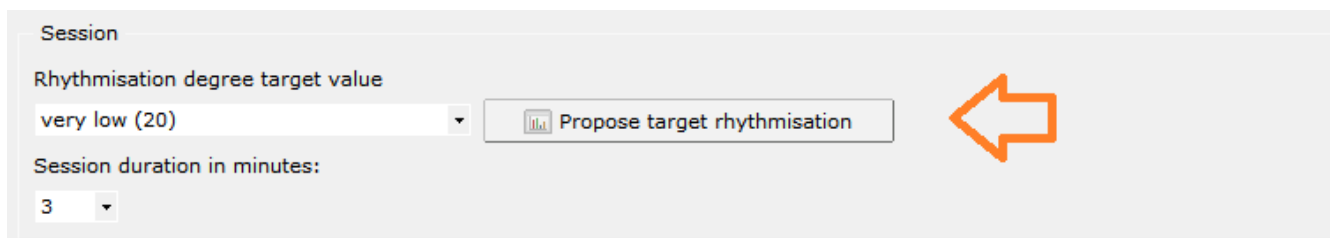
For the beginning, we recommend 3-5 minutes. Best 2 or 3 times daily. Over time, the duration can be increased (possibly also by lowering the daily exercise frequency).

Rhythmization degree target value (difficulty level of the exercise)

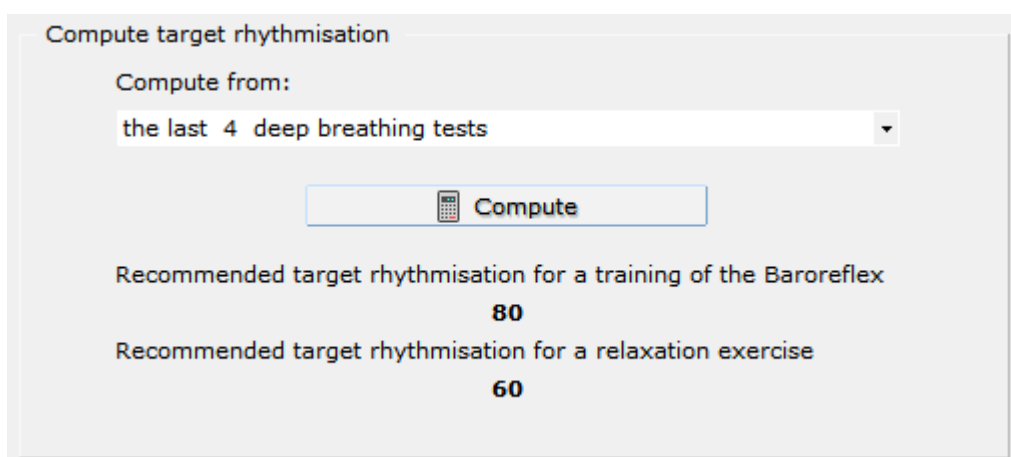
It is important to adjust the HRV biofeedback for each individual subject. A good dynamic should be seen in the reproduction of the current coherence (color chart, balloon rises and falls, Qiu glows green and red, ...). It makes little sense for the practitioner, when e.g. the color is constantly red, no matter how much he tries to breathe calmly and to relax mentally. Also e.g. a color chart, which is always green, no matter whether the practitioner breathes calm or rapid is senseless.

Therefore the difficulty of the exercise has to be adapted to the subject's basic HRV. The best results are obtained from the results from the basic measurements (Short-Term HRV and Deep Breathing Test). Subjects with poor results should be set to a low level of difficulty.

You will find a function for calculating the suggested default value from the Deep Breathing Test in all biofeedback types.



Here, a value is calculated and suggested from the last or the few last Deep Breathing Tests.



A value for the relaxation training or the baroreflex training is calculated and proposed.

Qiu and HRV-Scanner

The Qiu

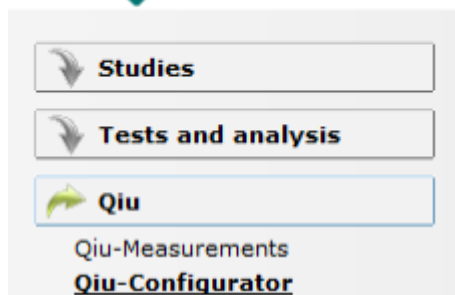


The Qiu is an easy-to-use, handy HRV biofeedback system with integrated memory for over 500 biofeedback exercises including date, time and heart rate curve. With the Qiu, your subjects can practice effectively and comfortably to their specifications at home or on the move, without having to rely on a PC or laptop.

The saved data will either be transferred to the Qiu module of your HRV scanner via the myQiu platform (cloud), via e-mail or the next practice visit via USB for further evaluation.

Each Qiu can be individually adjusted to the subject by means of the Qiu module of the HRV scanner. This allows you to optimally adapt the prescribed breathing, the difficulty and the duration of the biofeedback exercise to each subject.

The Qiu-Modul in the HRV-Scanner-Software



The Qiu module in the HRV scanner software allows the administration and evaluation of any number of Qiu measurements, as well as the individual configuration of the Qius for your subjects. The module is organized in two menu items:

- *Qiu-Configurator*
- *Qiu Measurements*

Qiu-Configurator

With the Qiu configurator, you can customize the Qiu for each of your subjects.

Connecting the Qiu to the PC

To activate the Qiu configurator, a Qiu must be connected to the PC.

Sometimes it can happen that the connection of the Qiu to the PC via USB does not work immediately. The following tips normally solve this problem:

- Use a different USB port
- Use a USB hub
- Reinstalling the USB drivers: please read this document https://www.biosign.de/download_Qiu/Qiu-Treiber-Installation.pdf
-

If the above tips do not solve your problem, please contact us (info@biosign.de).

Assigning a Qiu to a subject

A Qiu must necessarily be assigned to a subject, so that the stored measurements can be clearly assigned to the respective subject. A Qiu can only have one owner at a given time. However, a subject can be assigned several Qius. These assignments are stored in the subject master data in the "Qiu" tab and can be revoked there as well.

In a new assignment of a Qiu to a subject, the Qiu configurator checks if there are any measurements in the memory of the Qiu. These measurements should, unless they are from the subject to whom the Qiu is to be assigned, be deleted. Otherwise there is an incorrect assignment of these measurements.

Configuration of the breathing display on the Qiu

The Qiu can display the desired breathing rhythm with its blue LEDs. You can program different respiratory rates or completely disable the breath indicator. If you want to define your own breathing rhythm, select "individual". You can then set the values for inhalation and exhalation yourself.

Determine the exercise difficulty

The difficulty of practicing determines which achieved degree of rhythmicity of the Qiu indicates a positive (green) feedback.

The exercise difficulty should be carefully selected and depends on the desired goal of the biofeedback. In biofeedback exercises where relaxation, improvement of body perception and emotional components are in the foreground, the exercise difficulty should be set so that even at submaximal depth of respiration, a positive feedback is achieved.

Exercises to improve HRV and neurovegetative regulation require deeper stimulation of the underlying regulatory circuits and should therefore be performed with a higher exercise difficulty.

The standardized RSA measurement, which you can carry out with the HRV scanner under "Measure and evaluate", provides a clue for the correct default value. In the Qiu Configurator you will find under the menu item "Miscellaneous" the option "Suggest default value", where from the results of the last RSA measurements the optimal default value is estimated according to the purpose of the exercise.

As a safety precaution, after completing the configuration, subjects should conduct a biofeedback exercise with the newly programmed Qiu under supervision to ensure that the subject is able to reach the set target but may not be under-challenged.

Set the exercise duration

Here you can set the duration of the exercise between one minute and 20 minutes. The Qiu then automatically shuts off when the exercise time is reached. At the beginning we recommend an exercise time of 3-5 minutes.

Configuring the brightness of the biofeedback

The Qiu has two options for optical biofeedback, color-coded or intensity-coded biofeedback. Levels 1 through 7 set the brightness of the color-coded biofeedback, and Level 8 activates the intensity-coded biofeedback, which is primarily intended for users with red / green weakness. It is recommended to set the highest possible brightness levels so that the Qiu can also be used in daylight.

Note: All important settings of the Qiu can also be made directly on the device (see Qiu operating instructions)

Additional functions

Set the date / time of the Qiu

Before the subject begins to practice Qiu, the Qiu's date and time must be set correctly. This is the only way to correctly manage the Qiu measurements in the exercise plan later on and to calculate the compliance.

Clear the Qiu's measurement memory

When a Qiu is reassigned to a subject, it is necessary to clear the Qiu memory to avoid accidentally reading old measurements that are not from the current subject.

Qiu Signal Check

This feature allows you to see in real time the pulse signal and the derived heart rate and rhythmization curve. This feature is particularly useful for finding a suitable exercise and holding position for the Qiu in the subject's hand. For example, in subjects with low blood pressure or circulatory disorders, the pulse amplitudes in some parts of the hand (e.g., the ball of the thumb) are too low for reliable registration of the heart rate. With the aid of the display of the measured pulse wave in real time, different holding positions can be tried out and the most suitable one can be determined.

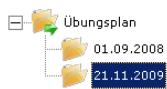
Ear clip as an alternative

If no good biosignal is found via the built-in sensor, we recommend using the ear clip as an alternative. Please note that the ear clip must always be inserted into the Qiu before switching on the Qiu. The Qiu searches for external sensors when it is switched on. If no external sensor connected is found, the integrated sensor will be used, even if subsequently an ear clip is plugged in.

If the Qiu cannot take a sufficiently good pulse signal with the ear clip, it helps to rub the earlobe a little with your fingers or to change the position of the ear clip on the ear a little.

Qiu measurements

Defining the exercise plan by day of the week and time of day



Uhrzeit	MO	DI
1.00		
2.00		
3.00		
4.00		
5.00		
6.00		
7.00		
8.00		
9.00		

To edit the exercise plan, click on "Qiu Measurements" in the Qiu module. From the subject list above, select the correct subject and then the "Exercise Planner" tab.

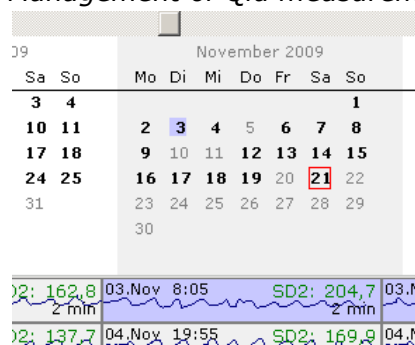
For each subject, a training plan with the exercise times can be created.

To schedule a biofeedback exercise for a particular day at a specific time, simply click on the appropriate cell in the table. Once you have set all practice times, click on "Assign the exercise plan to the subject from now on" to activate the new exercise plan.

Please note that there is a maximum of one exercise plan per day. The new exercise plan is valid from the day of creation until it is replaced by a new exercise plan. The exercise plan history to the left of the table shows you chronologically all previous exercise plans of the subject. By clicking on an entry in the list, the corresponding exercise scheme is shown in the table.

In the later compliance overview, the actual exercise times are compared with the exercise plan automatically, so that you can assess the test person's compliance at a glance.

Management of Qiu measurements



Click "Read Qiu Measurements" to transfer the Qiu data to the HRV scanner. All measurements in the connected Qiu that have not yet been transferred are now transferred to the HRV scanner software. Afterwards the exercise data will be evaluated automatically and entered in the calendar. Use the scroll bar above the calendar to move through the calendar.

Click on a calendar month to display all measurements of this month. Bold calendar days of a month indicate that exercises were performed that day.

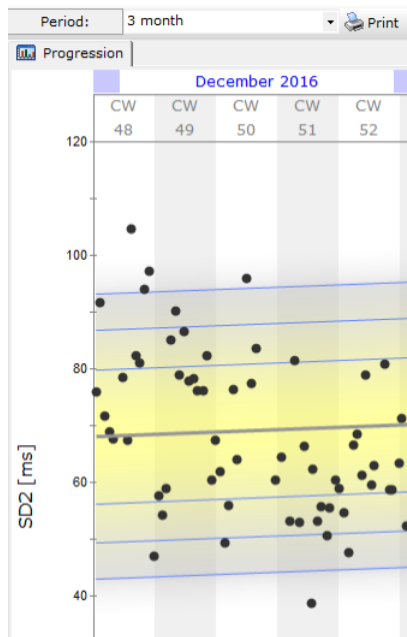
If you click on a single day with the mouse, all measurements of this day will be marked blue in the measurement overview.

Rework the measurement

To zoom in on a single measurement, click on the measurement in the measurement overview with the mouse. The selected measurement is now displayed in the large diagram below the measurement overview. You can now rework this measurement or remove it from the evaluation, if the exercise has cannot be evaluated due to too many artifacts. To edit, click "Edit", to remove, click "Do not use".

Note: Careful post-processing is important so that only artifact-free and high-quality measurements are used in the subsequent evaluation. If post-processing due to e.g. poor quality of data is not possible, the measurement should be marked as unusable (click on "Do not use")

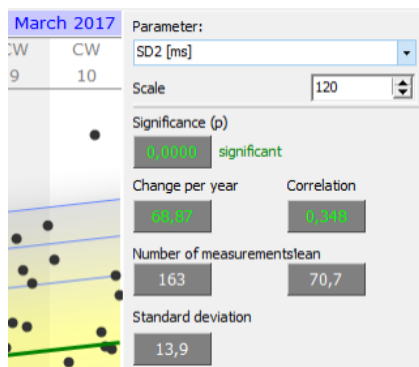
Overview of the exercise success with statistical evaluation



Due to the many HRV data collected with the Qiu when used regularly, changes in HRV are much better documented than with occasional HRV measurements. Statistical testing for linear (Pearson) correlation of HRV values over time enables reliable identification of systematic trends in the development of HRV.

Click on "Progression" in the bottom of the calendar to get the overview of the HRV value development. You can set a timeframe for viewing between 1 month and 2 years for "Period". With the scroll bar below the diagram, you can display and analyze any time window. To select from different HRV parameters, use the "Parameter" drop-down list.

Statistical evaluation:



For all displayed measurements in the diagram, a correlation analysis according to Pearson is performed. The correlation coefficient r (range - 1 < r < 1) indicates the degree of correlation between HRV and time. The statistical significance p shows whether the trend found is coincidence or a systematic change. A p -value < 0.05 is considered statistically significant (green marked P-value). P-values greater than 0.05 indicate a random trend (red marked P-value). With a p -value < 0.05, it can be assumed with a probability of error of 5% that there is a systematic influence on the HRV.

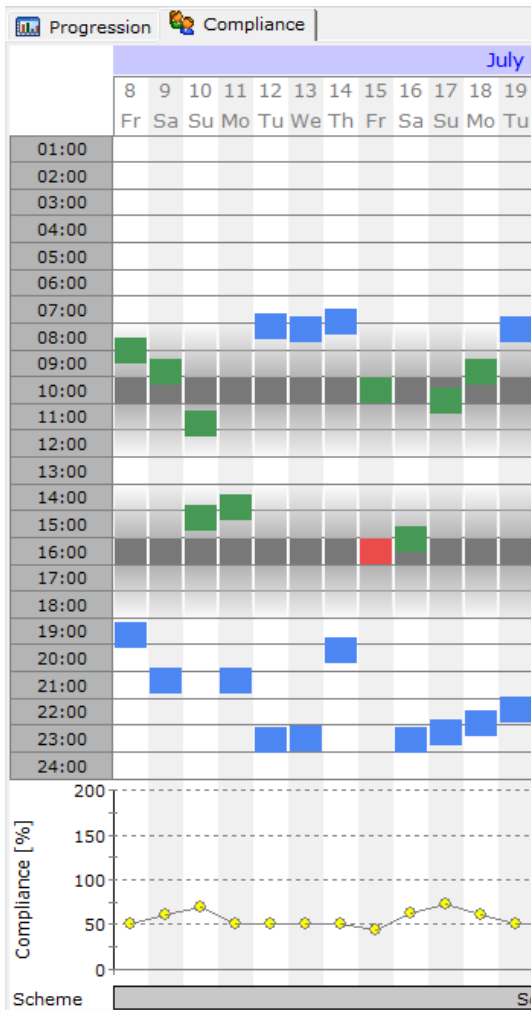
In order to estimate the size of the HRV change, the change in the HRV is extrapolated to one year and displayed ("change / year").

Note: There is a systematic, negative trend of HRV that affects all subjects equally, namely the age-related decline in HRV. Approx. 1-2% of the HRV is lost every year (based on the baseline of a 20-year-old). A negative trend in this size is therefore considered normal. (Cave! Stress Index (SI): The SI becomes larger with decreasing HRV = positive trend)

Filter settings

In the case of a large number of Qiu measurements, strongly deviating measurement results can occasionally occur due to artifacts, measurement errors or an acute illness. In order not to influence the trend analysis, it makes sense to remove these outliers from the analysis. To avoid having to search and manually exclude each of these measurements in the calendar, you can filter the data before analysis. Activate the checkbox "Filter active". By clever setting of the filter limits, all erroneous measurements can be excluded as a rule.

Overview of Exercise Compliance, Compliance Index

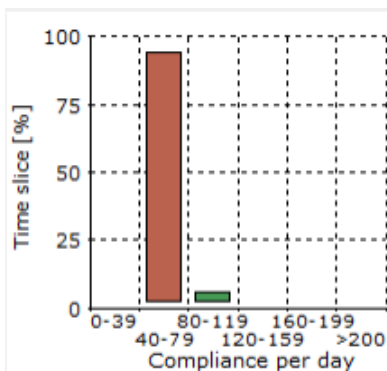


The compliance overview makes it clear how well your test person adheres to the given exercise plan. For this purpose, the times of the Qiu measurements are compared with the exercise plan and displayed graphically



For each day, the daily compliance is calculated. A compliance of 100% means an exact fulfillment of the exercise requirement on this day. Compliance greater than 100% means overfilling the constraint, i. the subject has done more than he should.

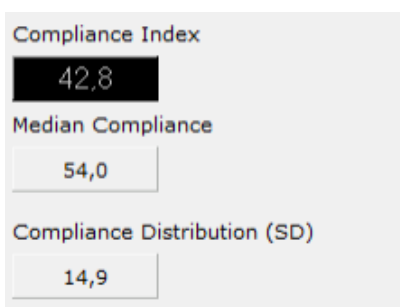
Correspondingly, compliance smaller than 100% means too little practice on the subject.



The compliance diagram below the compliance overview shows the compliance process in the selected time frame. A summary of compliance is provided by the histogram. The height of each column indicates the number of days (in percent) in the period displayed that daily compliance is equal to a value within the class boundaries of each pillar. In the histogram on the right is e.g. about 90% of the days the compliance between 40% -79%.

By means of the check box "Evaluate time deviation" you can specify whether deviations from the given time are included in the calculation of the compliance.

If the checkbox is activated, late or premature practice will reduce compliance. If the measurement time deviates from the time of specification by more than two hours, the compliance of this measurement is reduced to 50%. Within the range of two hours, the compliance adjustment is fluent, for example with a deviation of one hour, the compliance of the measurement is rated at 75%.



The compliance values of the days shown are used to calculate an index for compliance. Simply put, the Compliance Index is a mathematical description of the histogram. Relative to this is the proportion of the desired compliance (middle range of the histogram) to the width of the histogram (scattering). The Compliance Index can take values between 100 (consistently good compliance on all days) and 0 (no compliance).

HRV-Monitoring with the Qiu

Often, HRV is used as a parameter to objectify the success or progression of therapies aimed at improving parasympathetic function. For this purpose, a basic HRV examination (RSA measurement and short-term HRV) is usually performed at the beginning with the subject. This is followed by a measurement to start the treatment or, ideally still occasional measurements in the course of treatment, but due to the high cost, usually at longer intervals. Here, the risk that these few measurements do not reliably record the course of HRV is high.

Many things have a sometimes unfavorable, but short-term impact on the HRV. For example, mental stress states (quarrels, acute working stress), short infectious diseases or oversteering (sports) partly influence the results of the HRV measurements considerably. Such outliers can affect the course very unfavorably.

Therefore, it makes sense to give the subjects during a therapy a Qiu. On the one hand there is a training of the parasympathetic nervous system, on the other hand you get so a large number of measured values. Comparable to the blood pressure diary, the Qiu provides a valid documentation of the HRV.

Ideally, the volunteer's measurements are made available to the therapist via the cloud virtually in real time for inspection by the myQiu platform. Subject and therapist synchronize the measurement inventory via the myQiu platform. Using the HRV scanner, the therapist can view and evaluate all the subjects' measurements (Qiu, myQiu, PC biofeedback, ...).

An extension to smartphone apps and data transmission via Bluetooth, as well as the integration of external sensors (smartwatches, BT-Qiu) is in preparation.

Instruction

The success of the biofeedback exercise and the usability of the measurement data obtained depend strongly on the good preparation and instruction of the subject in the Qiu. The time you invest here saves you a lot of effort later on when reworking poor quality measurements.

The briefing should therefore answer at least the following questions from the subject if possible:

How do you turn the Qiu on / off?

Press and hold the button until the blue LEDs on the breath screen indicate the on / off cycle.

How can I leave the setting mode if it was accidentally activated when switching on?

Press the button until the Qiu shuts off.

Which holding position is suitable?

The Qiu should be kept in a sedentary position with the hand on a quiescent surface well below the level of the heart (for example, a hand rest on the thigh).

Which sensor position is suitable?

Preferably, the fingertips of index, middle finger or thumb should be used. A suitable sensor position can also be found by means of the "Qiu Signal Check" function in the Qiu configurator of the HRV scanner.

How do I recognize an inappropriate sensor position?

At the beginning of each biofeedback exercise, the Qiu seeks the pulse for about 10 seconds. During this time he reflects the amplitude of the pulse optically in the form of blue pulsations. If these pulsations are absent, and the Qiu does not switch to biofeedback mode, or if the Qiu often interrupts the exercise to seek the pulse again, the pulse sensor is not optimally placed. In this case, it is recommended to stop the exercise, turn the Qiu off and on again, and select a different sensor position.

The optical biofeedback stays permanently on red or green, no matter what I do?

The subject may have set a wrong level of difficulty in the setting.. If the subject is familiar with configuring the Qius with the button on the Qiu, he can control this himself, if not, the setting would have to be checked by you.

What does the wandering blue LED light at the equator of the Qiu mean?

The row of blue LEDs indicates the direction and speed of inhalation and exhalation of the volunteer during HRV biofeedback. Conveniently, the subject has exercised this under supervision for a few breaths to ensure safe execution.

Why does the Qiu light up brightly when it turns on?

During power up, the battery level is checked under load, so the Qiu is switched to maximum brightness for one second.

After the bright light when switching on the Qiu flashes recently red once again, why?

The charge of the battery is approaching the end. There are still a few exercises that can be done, but spare batteries should be provided.

After the light comes on, the Qiu flashes red three times and then turns off, why?

The batteries / resp. Batteries are empty and should be changed quickly. Important: The currentless state during the change of the batteries should be as short as possible, because the clock in the Qiu stops during this time.

Does the time and date in the Qiu have to be reset after changing the battery?

It is not necessary to set the watch by the subject if the test person has changed the batteries quickly. The clock will continue to run at the point where it has stopped, with full batteries installed. The short runtime difference of usually a few minutes is of no practical importance for the assignment of the measurements in the HRV scanner.

How can the subject change the batteries?

To open the Qiu, the transparent upper shell can be unlocked and lifted by turning it counterclockwise. The battery compartment can then be opened and the batteries removed. After inserting the batteries, closing the battery compartment and placing the upper shell, the latter is locked by a short clockwise rotation.

Note: Pay attention to the correct polarity of the new batteries.

Additional HRV tests

HRV supine/standing

HRV supine/standing measurement with or without blood pressure determination. Standard 5 minutes of supine/standing up/5 minutes standing, or freely configurable.

This test examines the physiological responses when changing the body position from lying to standing. Because there is a 5 minute phase of laying before standing up, the Short-Term HRV can also be carried out in this test. As a result, a separate determination of the Short-Term HRV can be committed and measurement time can be saved.

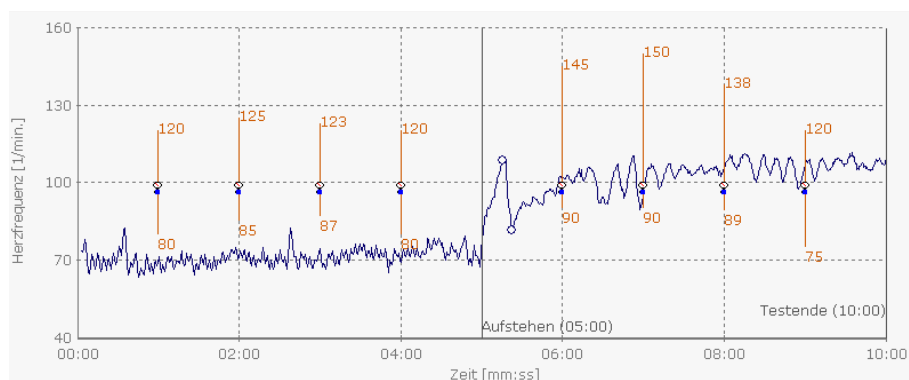
Immediately after standing up, the heart rate increases until it slows down significantly after about 20 seconds. The rapid increase in the heart rate is caused by a reduction in the parasympathetic activity, while the subsequent bradycardia is mediated by the baroreflex. The aim of the whole regulation is to ensure a sufficient blood pressure, because in the orthostatic the sudden shedding of more than half a litre of blood in the legs must be balanced. Therefore, in addition to the adaptation of the heart beat, there is also an increase in the sympathetic activity of the vascular system, combined with an engorgement of the vessels. In healthy persons, the orthostatic regulation is completed on average after approximately 20 seconds.

Age, sex, and exercise can affect the regulatory behaviour as well as metabolic factors, e.g. food intake, alcohol or nicotine.

A normal, physiological blood pressure regulation is reflected in a slight decrease in systolic blood pressure by 5-10 mmHg, an increase in diastolic blood pressure by 2-5 mmHg and an increase in heart rate between 5-20 beats/min.

The blood pressure should decrease systolic not more than 20 mmHg and diastolic not more than 10 mmHg. A more severe reduction in blood pressure is also called orthostatic hypotonic. Another misregulation is an excessive increase in heart rate while standing. The heart rate should not rise more than 30 beats per minute, compared to the lying level, or not exceed a value of more than 120 beats/min.

Example of an orthostatic measurement. Significant Ewing response (rapid increase in heart rate, followed by a marked drop in heart rate). Remarkable is the strong increase of heart rate while standing (> 30 beats/min).

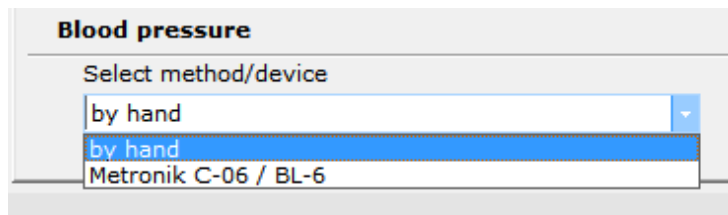


Note on implementation:

Be careful not to inform the subject too early about the time of standing up, because this creates an expectation that is associated with an increased sympathetic tone and can distort the result. The subject should stand still immediately after getting up without activating the leg musculature more than necessary, because the muscular pump is arbitrarily interfered with in the regulation of blood pressure and heart rate and thus the control power of the vegetative nervous system is no longer assessable.

Danger:

When performing the Ewing test, some people may experience syncope. The appropriate design of the test sequence must ensure that the test person does not suffer any damage during the occurrence of the syncope. (No sharp or sharp-edged objects in the vicinity of the volunteer, assistant staff in the immediate vicinity of the subject when standing up, which is able to absorb a sudden fall or to mitigate.)



Note: The blood pressure can be measured manually or using the Metronik C-06/BL-6 blood pressure monitor. Specify in the system settings which method should be used.

Long term measurements

Long-term HRV measurements can provide valuable insights regarding HRV during the day. The measurement is usually carried out with holter systems. We recommend using the Faros 180 from Mega Electronics. This device records the ECG and has acceleration sensors in the three axes.

The first step of the analysis involves the production of a heart rate graph as good as possible through processing the ECG. All other parameters and curves will be created on the basis of this in the second step.

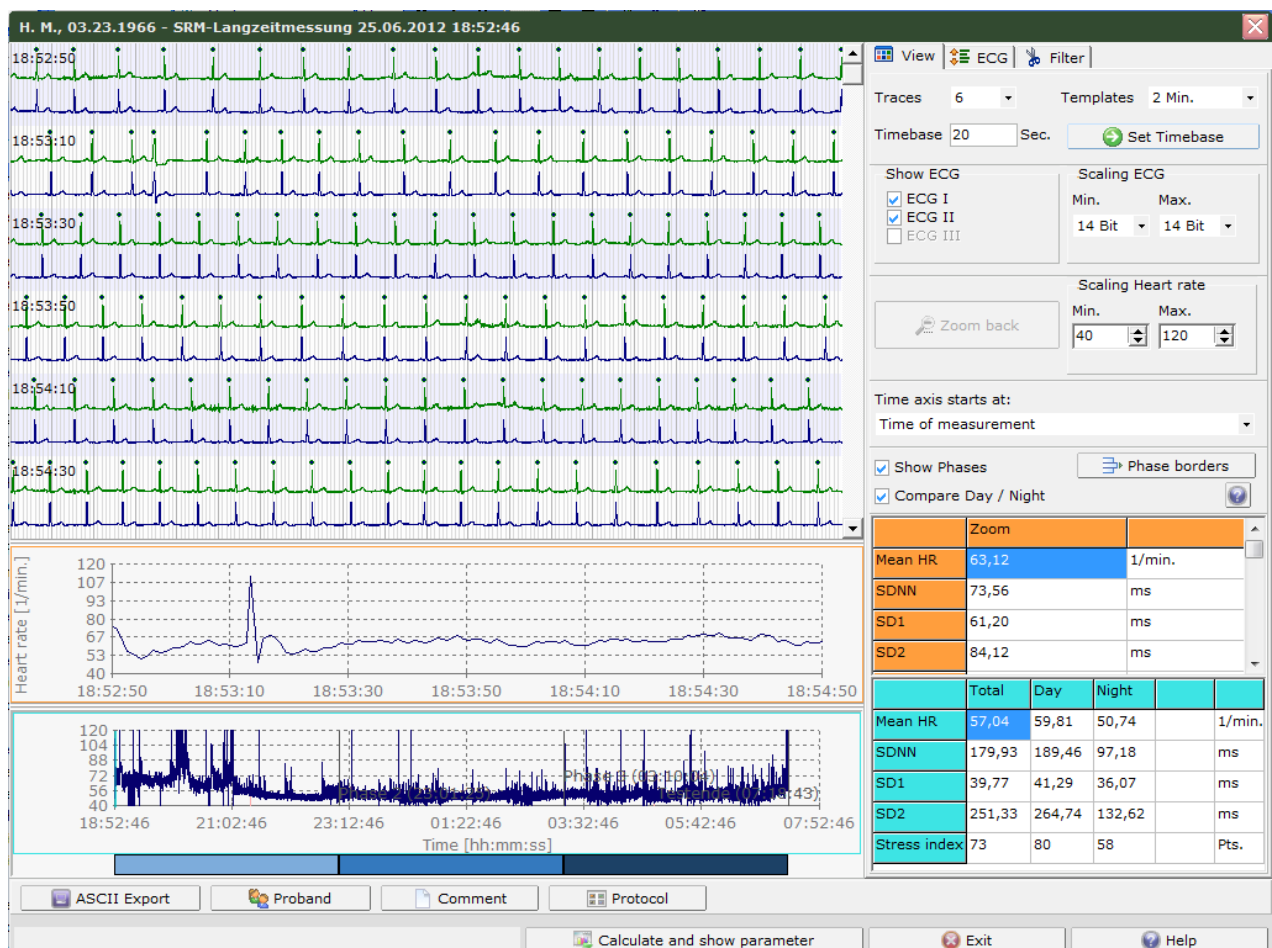


Fig.: Structure of the analysis window

Long-term Analysis - Step 1 - Diagrams

In the left part of the window you will see three diagrams and the phase bar, which displays the length of the individual phases of a measurement. The upper diagram shows the ECG, the two lower diagrams show the heart rate graph. The upper heart rate diagram represents the heart rate graph derived from the ECG above. The lower heart rate diagram shows the heart rate graph for the entire test.

Note:

You can alter the sizes of the diagrams by dragging the two "splitters" (separation lines between the ECG and heart rate diagrams and between the two heart rate diagrams).

To scroll through the measurement click the scroll bar on the right next to the ECG diagram. You can also zoom in on any area in either of the diagrams by using the left mouse button. By clicking the undo button in the "display" tab the zoom can be undone. You can also achieve the same effect by pressing the right hand mouse button.

You will see the phase bar beneath the heart rate diagram. By dragging the mouse with the left mouse button held down you can split the measurement into three different phases each of which will be analysed separately.

Long-term Analysis - Step 1 - View

Here you can configure the diagrams

The screenshot shows the 'View' tab of the HRV-Scanner configuration window. It includes settings for the number of traces (6), templates (2 Min.), timebase (20 Sec.), and scaling for ECG and heart rate. There are checkboxes for showing ECG I, II, and III, and a 'Zoom back' button. The 'Time axis starts at' dropdown is set to 'Time of measurement'. There are checkboxes for 'Show Phases' and 'Compare Day / Night'. At the bottom, there are two tables showing measurement data.

	Zoom	
Mean HR	63,12	1/min.
SDNN	73,56	ms
SD1	61,20	ms
SD2	84,12	ms

	Total	Phase 1	Phase 2	Phase 3	
Mean HR	57,04	65,02	50,74	53,68	1/min.
SDNN	179,93	194,27	97,18	134,58	ms
SD1	39,77	44,54	36,07	37,12	ms
SD2	251,33	271,10	132,62	186,67	ms
Stress index	73	118	58	43	Pts.

Number of lines in ECG diagram

Time base

Length of the ECG displayed in a given track in seconds. To accept the setting please click on "set Time base".

Templates

Templates display an excerpt from the measurement with a predefined length, whereby the number of tracks and the time base will be set such as to produce an optimised display.

Scaling ECG

The ECG is saved in the HRV-Scanner in a 16-bit Format with plus/minus signs, i.e. from +32767 to -32767. This corresponds to a number range from +15 bits to - 15 bits, whereby often only a small part of the number range will be used, depending upon the ECG amplification, so that it will be necessary to configure a correspondingly smaller number range in order to be able to see the ECG.

Note: Please note that changing the scale here is only relevant to the display and not to the recognition of the R-waves in the "ECG" tab.

Scaling Heart rate

Here you can set the Y-axis of the heart rate diagram.

Time Axis starts at

Here you can decide, whether the time axis should begin with t = 0 or with the actual time of the measurement.

Show Phases

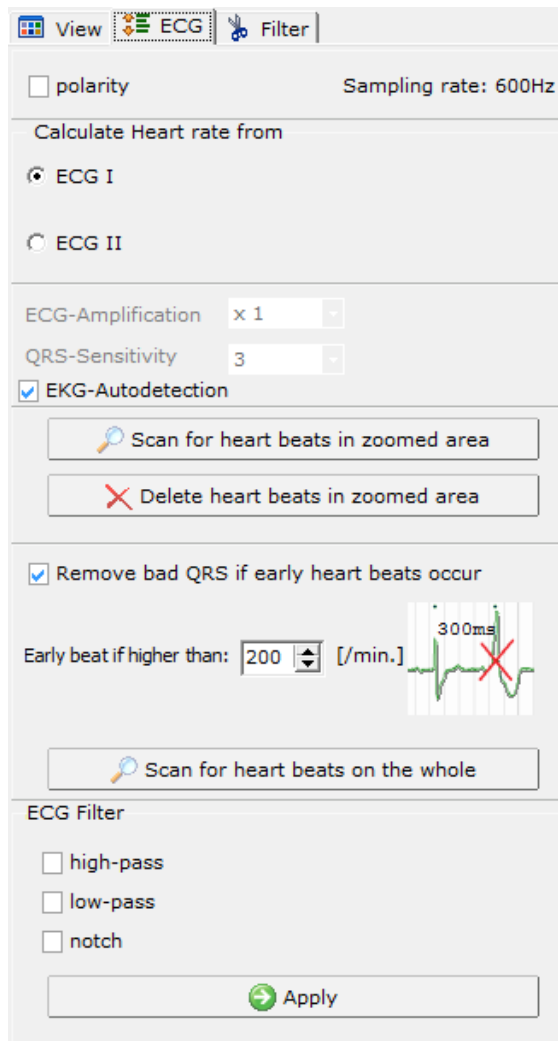
Here you can decide, whether the measurement should be subdivided into three phases, and/or whether the division should be displayed and taken into account in the analysis.

Phase borders

Here you can set the phase limits (start and finish). The window for editing the phase limits will appear. The phase limits are entered in this window depending upon the configuration of the time axis. If you have selected (t = 0) then the time entered will relate to the interval from the start of the measurement, otherwise please

enter the actual times for the phase limits. By clicking "accept" the phase limits will be included in the measurement and the display.

Long-term Analysis - Step 1 - ECG



Polarity

Reverses the polarity of the ECG. This is useful if, for example, the electrodes have been applied the wrong way round. After reversing the polarity the QRS analysis to determine the R-waves should be repeated.

Calculate Heart rate from ...

If several ECG tracks are recorded then this is where you can select which track should be used to determine the heart rate.

ECG Amplification and QRS Sensitivity

This affects the settings for the QRS analysis. The greater the configured values the more sensitive will be the QRS analysis. This also increases the likelihood that minor artefacts will be falsely identified as R-waves.

ECG-Auto detection

The settings for the QRS analysis will be set automatically.

Scan for heartbeats in zoomed area

Searches for R-waves within the ECG diagram. Sections of the analysis outside the ECG diagram will not be analysed.

Delete heartbeats in zoomed area

Deletes all R-wave markers within the ECG diagram. Does not affect sections of the analysis outside the ECG diagram.

Remove bad QRS if early heartbeats occur (only available with actual ECG, not available for measurements from RR intervals and artificially created ECGs)

Sometimes two identified R-waves are so close together than it is unlikely that both R-waves are the result of a physiological sinus rhythm. This is often the result of an extra beat or an artefact in the vicinity of a normal heartbeat. If the "remove premature QRS" function is activated then after clicking on "Find All QRSs" the form of R-waves in close proximity will be analysed and compared to the rest of the R-waves. The R-wave whose form comes closest to that of the majority will be retained and the other will be rejected as an artefact. Using the entry field you can specify the point as of which two R-waves will be regarded as premature and checked for form similarity.

Scan for heartbeats on the whole

Starts a search for R-waves throughout the entire ECG, whereby existing markers will be deleted.

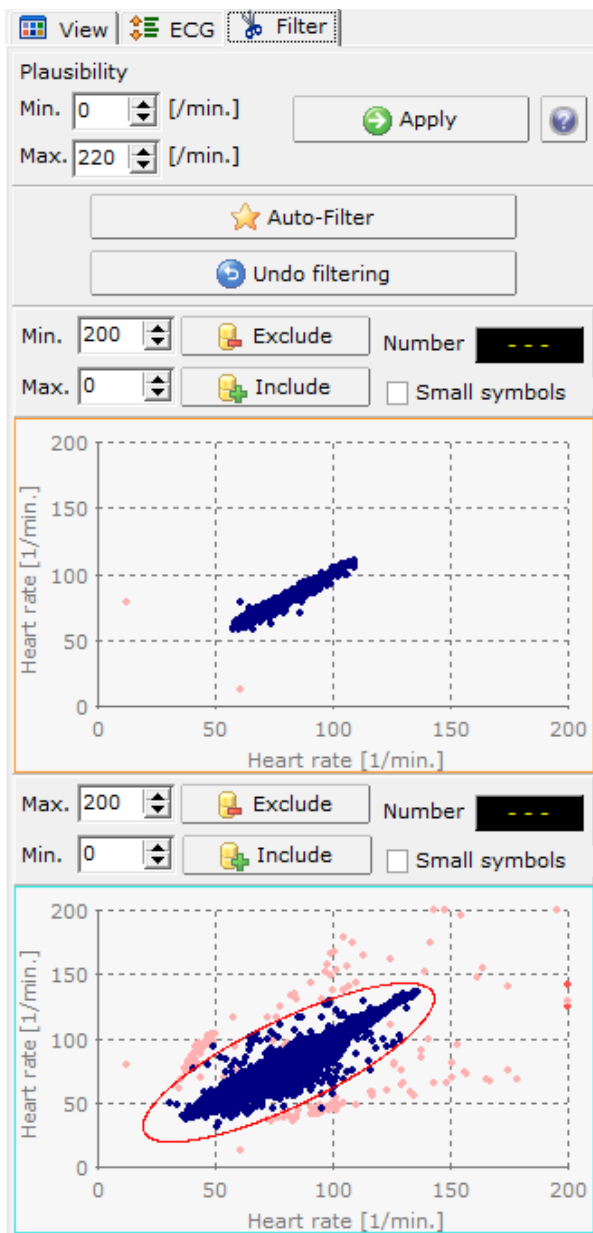
ECG Filter (only available with actual ECG, not available for measurements from RR intervals and artificially created ECGs)

Using this function you apply various different filters to the ECG. The high-pass filter removes slow signal element, e.g. base line fluctuations. The low-pass filter can remove high frequency interference. The notch filter is used to reduce any network hum.

Note: Measurements generated through the import of RR lists are given an artificially generated ECG. In this case the filters are not available as there can be no faults in the signal.

Long-term Analysis - Step 1 - Filter

Use the various filters to remove as many artefacts as possible. Only in this way can a valid analysis of the measurement be produced.



Plausibility

A normal heart rate graph (sinus rhythm) is unlikely to contain extremely high or low heartbeat frequencies. Usually any such exceptions are the result of artefacts or extra beats. Set the upper and lower limits in order to exclude such artefacts right from the start.

Undo filtering

Reverses the last Poincaré filter.

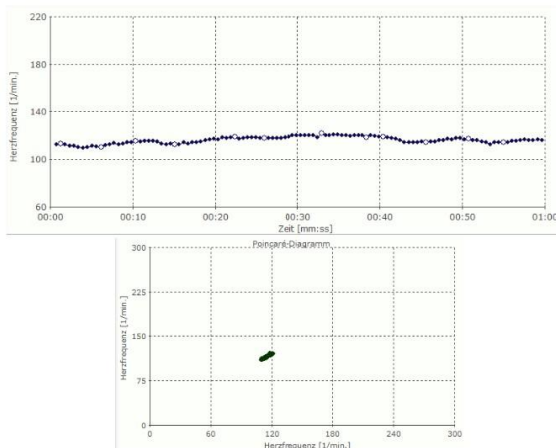
Poincaré-Filter

see below

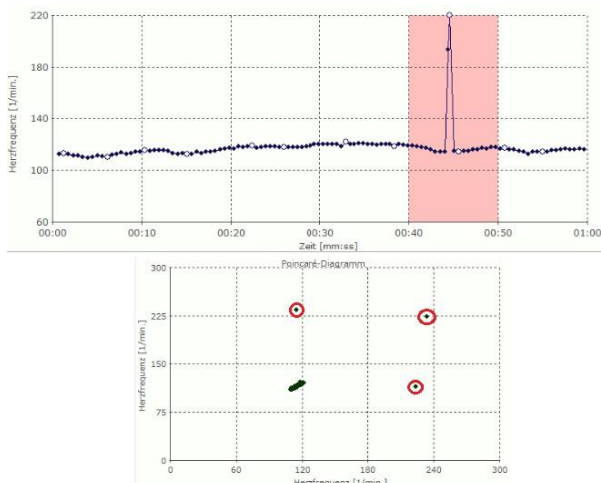
Poincaré-Filter

There are two graphic filters available based on so-called Poincaré plots. Poincaré diagrams are particularly well suited for identifying outliers in the heart rate graph.

The following example shows an artefact-free heart rate graph and below it the corresponding Poincaré diagram.

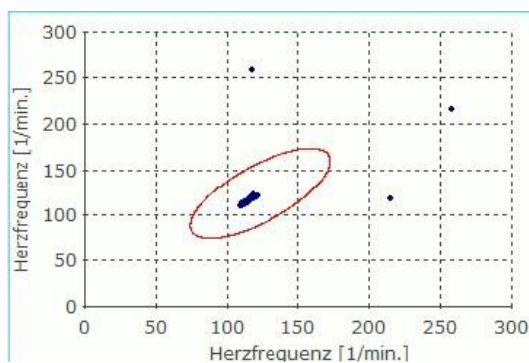


Now the same heart rate graph with several artefacts:



The exceptions can be clearly identified in the Poincaré diagram as points outside of the point cloud (marked with a red circle) and can now be easily filtered out:

to do so simple hold down the left mouse button and drag an ellipse around the point cloud formed by the real heartbeats (see image).



The events are displayed in the heart rate diagrams and in the HRV graph.

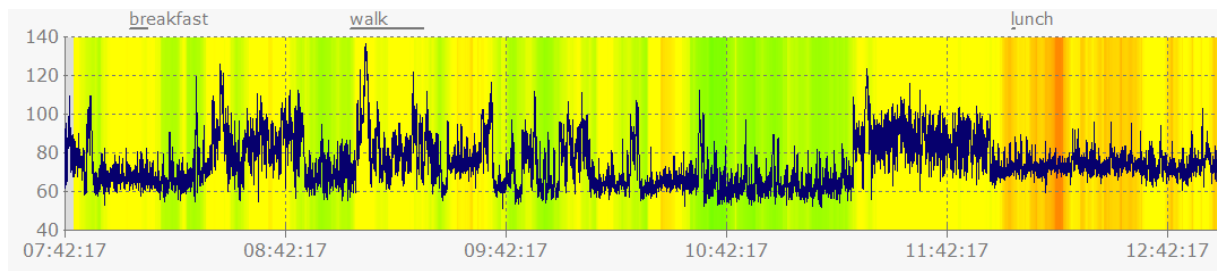
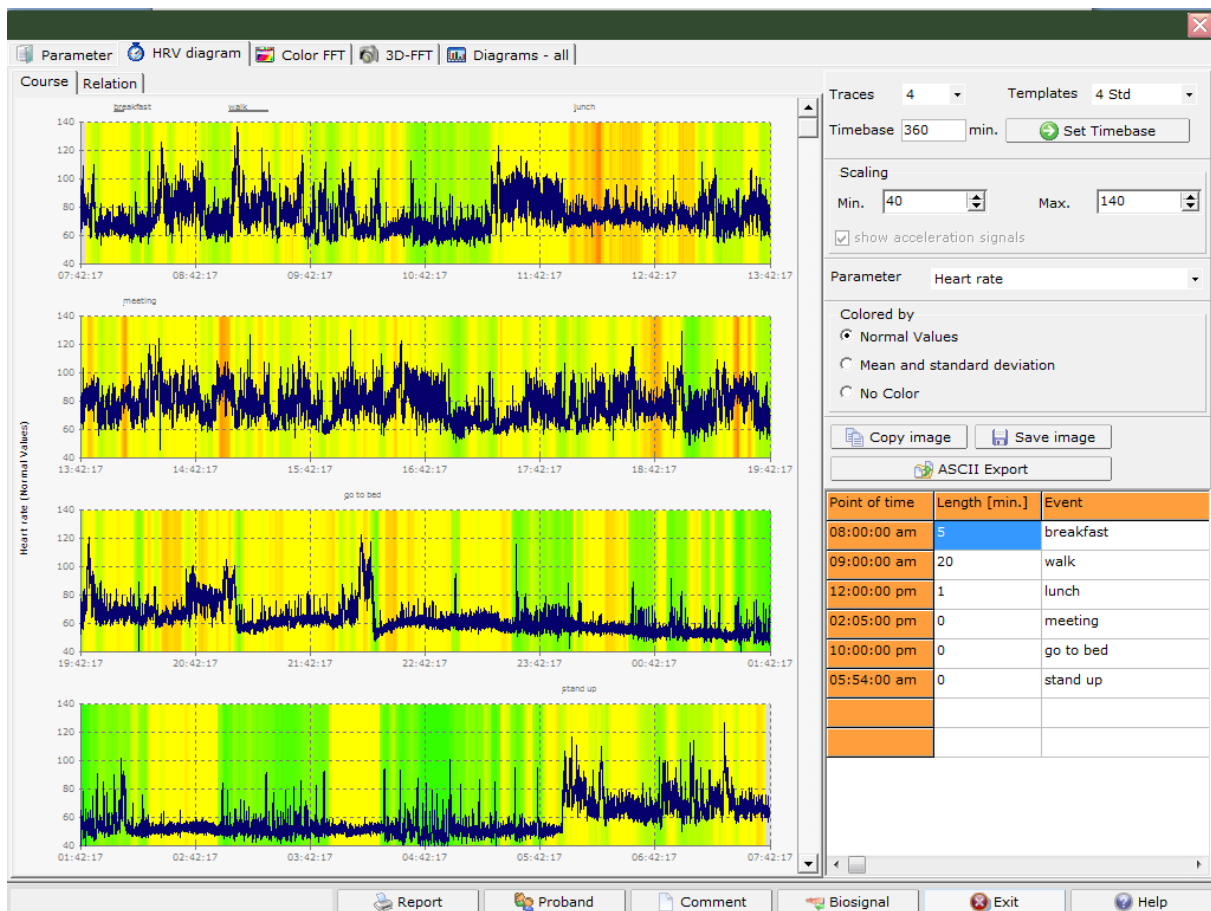


Fig.: Entries from the protocol list in the HRV graph

Long-term Analysis - Step 2

In addition to the usual depiction of the analysis in the HRV-Scanner (parameter list, bar chart, heart rate graph, Poincaré diagram, spectral analysis for the entire measurement and up to 3 freely configurable phases, colour FFT, 3D FFT) the new long-term analysis module includes a colour shaded HRV graph.



Analysis window overview - Step 2

Abb.: Fig.:

Long-term Analysis - Step 2 - HRV Progress

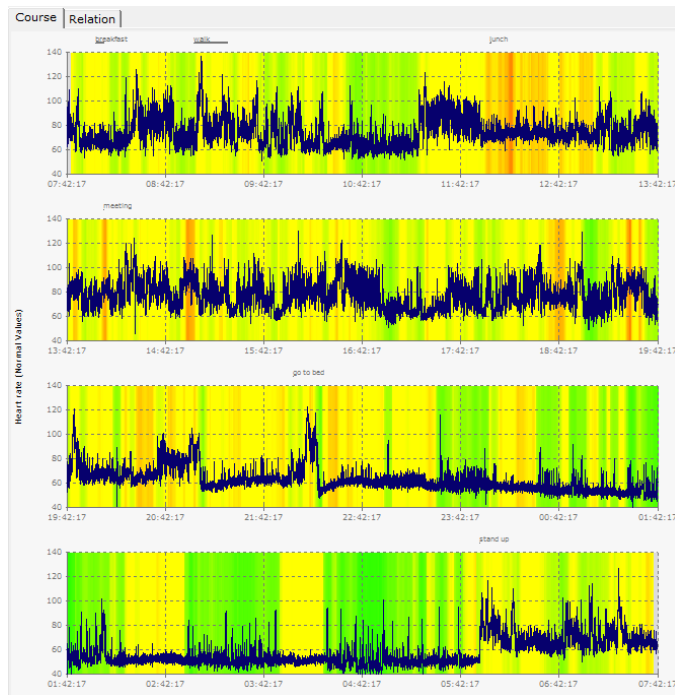


Abb.: HRV progression

In comparison, the percentage distribution of the recorded sections for the adjusted parameter is shown in the comparison total/phase 1 - 3 or in the day/night comparison.

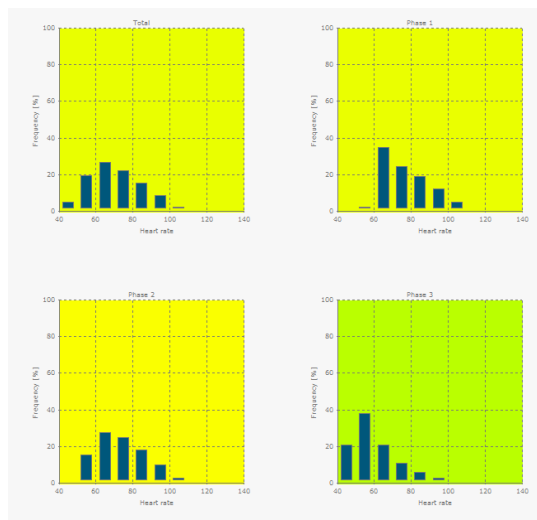


Fig.: Comparison overall/phases (1-3)

The colours displayed in the HRV graph are determined by the ranking of the age correlation of the Short-Term HRV measurement as a percentage. To this end the long-term measurement is divided into a number of short-term measurements (5 minutes each) and the ranking of the age correlation is calculated as a percentage for each section.

Alternatively the colour can be calculated on the basis of "average value and standard deviation". It is also possible to display graphs without colour shading.

The following parameters can be selected for the HRV graph display:

heart rate, average HF, St. Dev., SD1, SD2, stress index, in (stress index), power HF, power LF, power total, in (power HF), in (power LF), in (power total), LF/HF Ratio, percent ranking (short-term HRV), degree of rhythmisation.

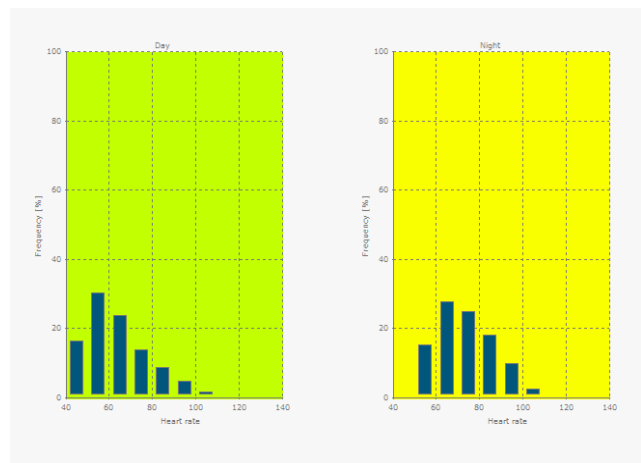


Fig.: Comparison day/night

Extended 24h analysis

Introduction:

With the advanced 24h analysis, there are several new features available that allow an even more accurate assessment of the 24 hour HRV:

- Detailed assessment of measurement quality in the 24-hour process.
- Analysis of abnormalities in HRV (percentage HRV parameters beyond 1% and 99% percentiles respectively) for day and night.
- Spiderweb plots with normative percentiles for many parameters for day and night.
- Assessment of nocturnal recovery (day / night shift HRV).
- Specific performance indexes for the sympathetic and parasympathetic, each for day and night.
- "Functional HRV Age": calculation of a functional HRV age as the biological age of the autonomous nervous system. A high functional HRV age may indicate an increased cardiovascular risk.
- Sleep: Scan for Obstructive Sleep Apnea (OSA) with calculation of the probability that OSA is actually present (Post-Test Probability).

Click on the "Extended 24h analysis" button in order to start the extended 24h analysis. Please note that you can move this evaluation window on the desktop independently of the actual HRV scanner window, so that you can view the additional evaluations in parallel to previous diagrams.

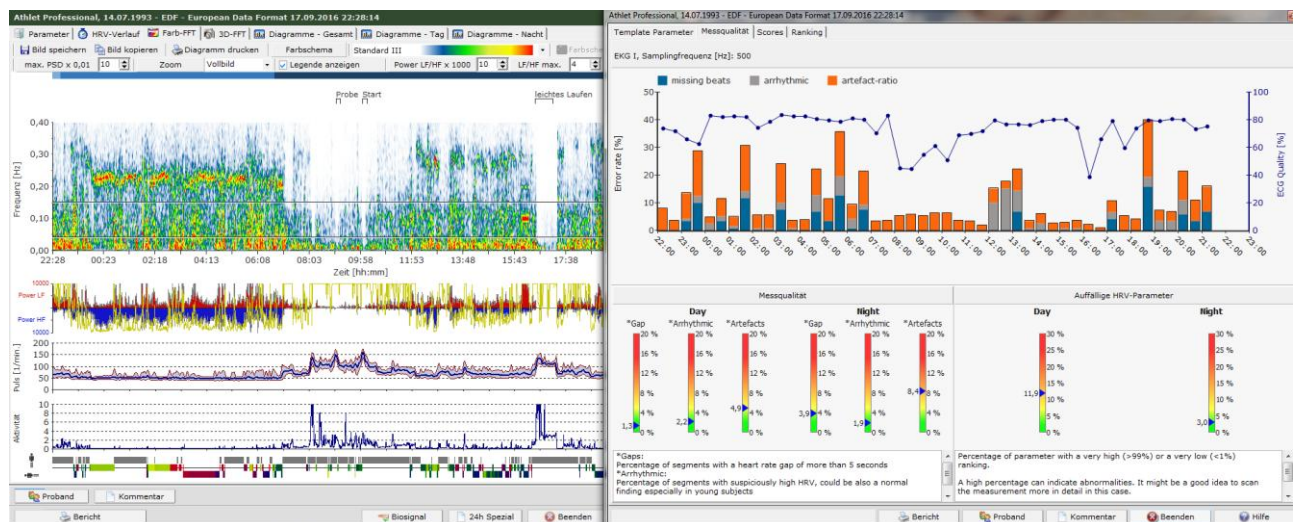


Image: Arrangement of the 24h analysis window next to the main window is possible

Detailed assessment of measurement quality

The basis of every HRV measurement is an artifact-free registration of the ECG curve. Motion artifacts, poor electrode contact, or other sources of interference, such as electrical noise, can lead to a poor quality ECG. This makes the recognition of the heartbeat difficult or it may result in errors in the calculation of the heart rate curve.

In order to assess the validity of an HRV measurement, it is therefore always necessary to consider the quality of the measurement. There are two new charts in the HRV scanner:

- Measurement quality broken down over time
- Measurement quality added up for the day the night

The following sources of interference are recorded:

Gaps

Specifies the percentage of segments containing gaps in the heart rate curve longer than 5 seconds. Gaps occur when, for example, an unfavorable ECG lead has been selected and the R-waves are very small and are not reliably detected by the QRS analysis. But gaps also arise when, for example, a severely blurred ECG (muscle and motion artifacts) leads to many false-positive detected R-waves, which are then filtered out in the second step.

Arrhythmia

Specifies the percentage of segments with conspicuously high HRV. In particular, rapid heart rate changes, as typical of arrhythmias or artifacts, are weighted. However, high arrhythmia levels are not proof of a possible arrhythmia, as children and athletic young adults sometimes have a very high HRV, but this is physiological. In our experience, falsely high arrhythmia levels no longer occur in subjects with sinus rhythm older than 30 years. In case of doubt, it is advisable to take a closer look at the ECG and the heart rate curve. Often, the artifacts are not sufficiently eliminated, or the heart rate curve has not yet been filtered.

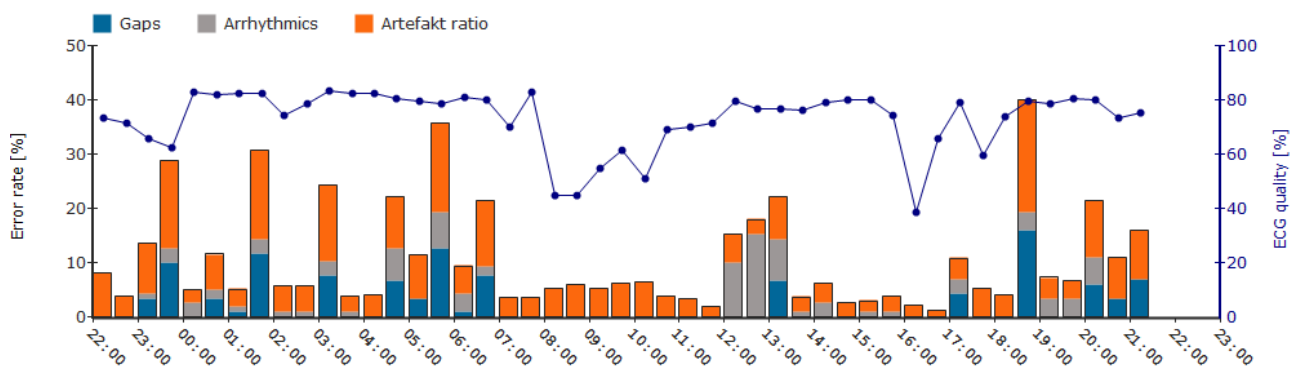
Artifact Ratio

The Artifact Ratio indicates the percentage of how many heartbeats were removed by filtering. The higher the ratio, the more heart beats were recognized, but classified by the user as not to the sinus rhythm and removed by filtering. The cause can usually be found in the ECG. In most cases, these are misrecognized R waves due to movement and muscle artifacts.

Note: If the heart rate curve has not yet been filtered, the artifact ratio is by definition 0%. But this is not to be confused with an artifact-free heart rate curve!

ECG quality

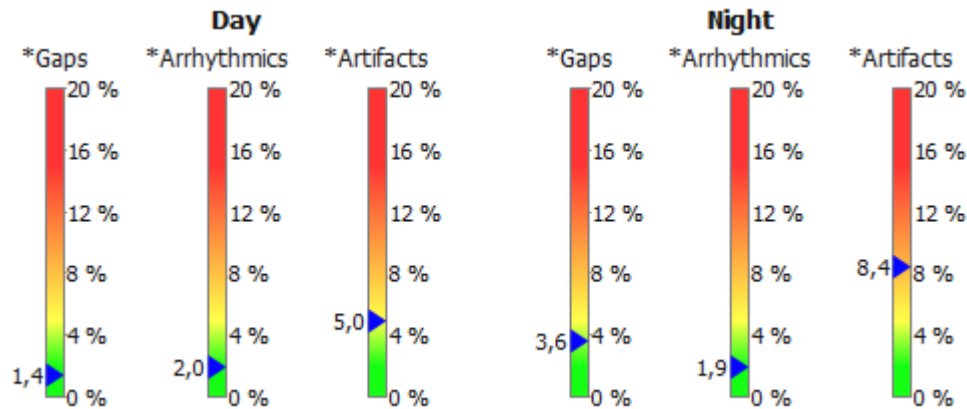
False or unrecognized heartbeats are usually caused by signal disturbances of the ECG. For this reason, the HRV scanner analyzes the ECG for typical disorders, e.g. net hum or motion artifacts and calculates an ECG quality between 0-100% for half-hour periods. Well-usable ECGs usually have an ECG quality of > 80%. Highly sinking ECG qualities are a sign of signal interference, e.g. during sports or as a result of poor electrode contact. The lower the ECG quality and the higher the interference in a certain period of time, the more restrained should the HRV of this period be interpreted.



Picture: Display of the measuring quality in the 24h-course. The individual sources of error (gaps, arrhythmia, artifact ratio) are displayed as error bars for every half hour, the ECG quality as a blue curve with an ECG quality for every half hour.

Note: If the 24h analysis was generated from a heart rate list (also called the RR or IBI list), there is no ECG quality indication due to the missing ECG.

The average error rates are reported separately for day and night. In general, the lower the error rates, the more plausible is the HRV analysis.

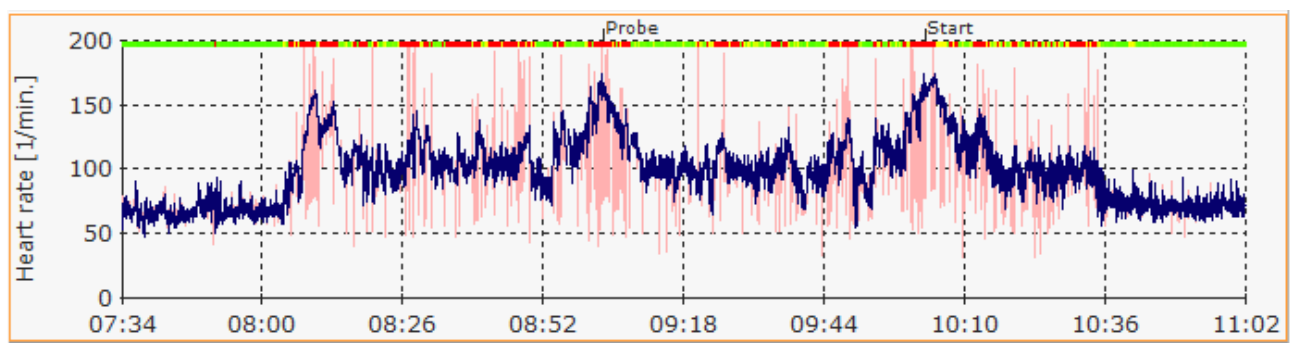


Picture: Average quality of measurement separated for day and night.

In the ECG study in healthy volunteers, from which the normal values for 24h HRV were derived, the error rates on average were: gaps: 0.1%; Arrhythmic: 1.8%; Artifacts: 1.1%. (The arrhythmia score of 1.8% on average in the study is not based on arrhythmias or artefacts, but is the result of numerous young study participants and their age-typical high HRV.) The arrhythmia value of the study participants older than 30 years was 0.2%).

Note:

The ECG quality is shown in the heart rate diagrams as a thin colored line according to the traffic light principle. As a result, indications of possible disturbances in the ECG signal are already obtained during the inspection of the heart rate curve. Since the calculation of the ECG quality is very computationally intensive and takes between 5-20 seconds, depending on the performance of the PC, the calculation has been moved to the background. Once the calculation is complete, the ECG quality is displayed. However, you can continue to work with the HRV scanner as you like, while the calculation runs in the background.



Picture: Display of the ECG quality according to the traffic light principle as a thin colored line at the top of the heart rate diagrams. In the above example, ECG disturbances are caused by motion artifacts during physical activity.

Abnormalities in the HRV

A good starting point for the HRV analysis is an overall assessment of whether it is a "normal" HRV measurement. "Normal" in this context means that most HRV parameters are in the normal range. For this purpose, the HRV scanner compares the respective result with the corresponding age-corrected standard value table of 67 different HRV parameters and uses this to calculate the respective rank value (ranking, percentile). Results beyond the 1% and 99% percentiles are considered "conspicuous". A high percentage of the "conspicuous" parameters may be an indication of a possible disorder in the autonomic regulation or a problem with the measurement quality.



Picture: 70-year-old male with vagal dysfunction and severe sleep apnea.



Example: 23-year-old competitive athlete with intensive training phases during the day and a restful night's sleep.

Spiderweb charts with normative percentiles

Similar to the existing ranking diagrams of the short-term HRV analysis, so-called spiderweb diagrams are now also available for the 24-hour analysis, which allow an evaluation of the HRV, see figure. The difference to the rank diagrams lies in the scaling. The ranking charts of the short-term measurements map the age-corrected percentiles (rank value) on a scale of 0% -100%. A conclusion on the underlying absolute HRV value is thus not possible. Different in the 24h analysis: The spiderweb diagrams in the 24h analysis show the absolute HRV value. This makes it easier to record changes from day to night. To determine whether it is a high, medium or low HRV value in comparison with the age group, the 95%, 50% and 5% percentiles of the respective age group are shown.

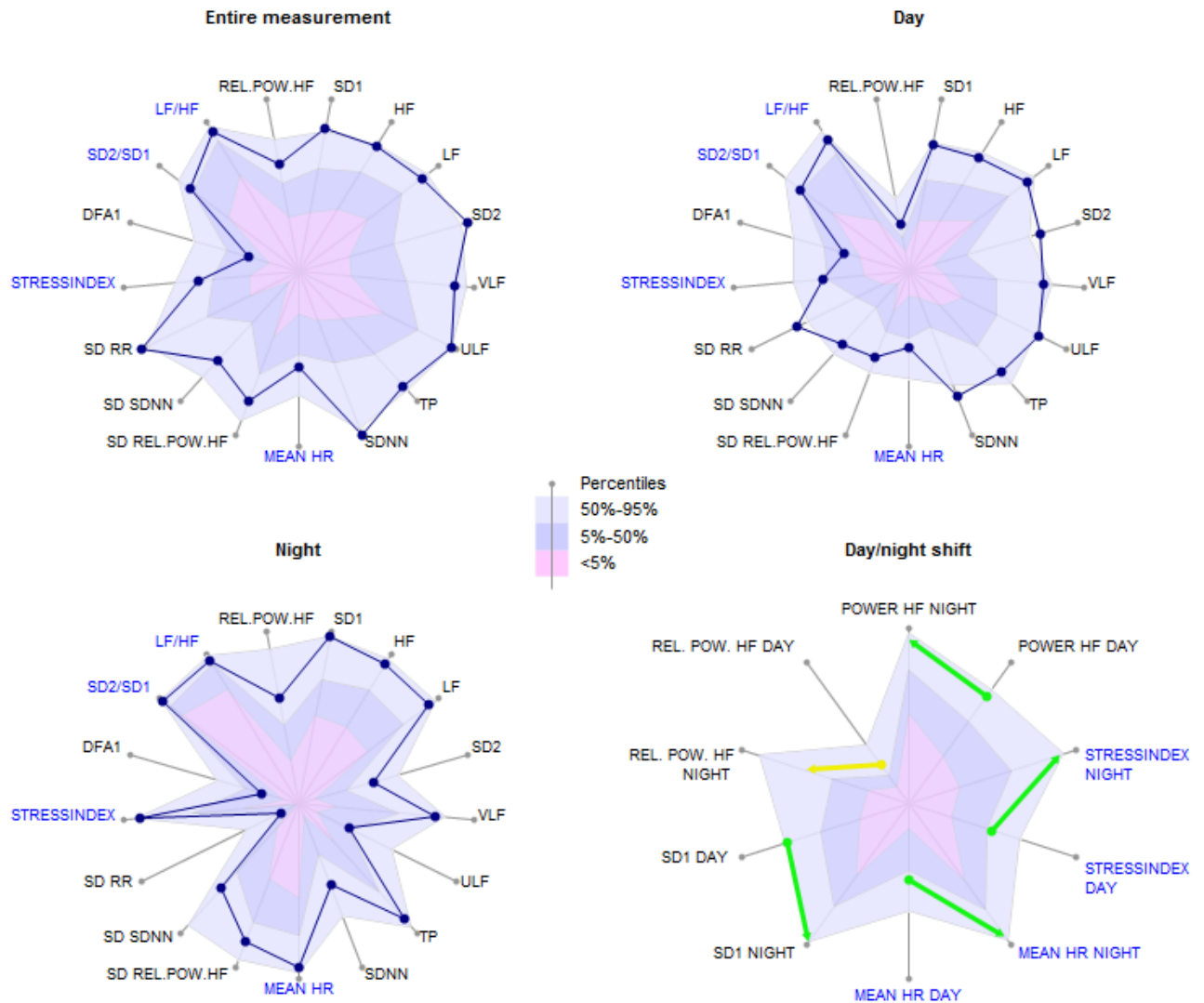


Image Spiderwebs: 23-year-old competitive athlete. Each spiderweb chart shows the 5%, 50% and 95% percentiles.

Scaling

The spiderweb diagrams are always scaled the same regardless of the subject, subject age and measurement period (day, night, total, shift). On the label of the absolute scales was omitted for reasons of readability. Due to the identical scaling, the diagrams are comparable with each other and between different subjects:

For example, on the above graph, you can see from the percentiles that the "Rel. Pow. HF", (relative power of the HF band) for most people during the day is significantly less than during the night. This corresponds to our intuitive expectation, because activities during the day require a certain amount of sympathetic activity, which leads to a reduction of rel. Power HF.

The spiderwebs show frequently used HRV parameters, which should normally not be missing from any HRV analysis. "Blue" parameter such as "Stress Index" or "Mean HR" indicate parameters where low absolute values are medically more favorable than large absolute values. The scale is interchanged with these "blue" parameters: the highest value of the scale lies inside the diagram, the smallest outside.

New in the HRV scanner are the parameters "SD RR", "SD SDNN" and "SD Rel. Pow. HF ". It is the standard deviation (SD) of the respective parameters. These are therefore measures of variation of the HRV and provide information on how strongly the individual parameters change in the respective time period (day / night / total). They are thus a measure of the change in the load. The greater the differences between stress and relaxation and the more frequent the load changes, the higher the standard deviation of HRV.

„SD RR“, also called SDANN: standard deviation of the mean value of the RR intervals in all five-minute sections of the entire record.

„SD SDNN“ Standard deviation of the SDNN of all five-minute sections of the 24-hour recording.

„SD Rel. Pow. HF“: Standard deviation of the relative power HF band of all five-minute sections of the 24-hour recording.

Note: The HRV Scanner calculates the SD-X values in moving windows with a window width of 5 minutes and a step of one minute.

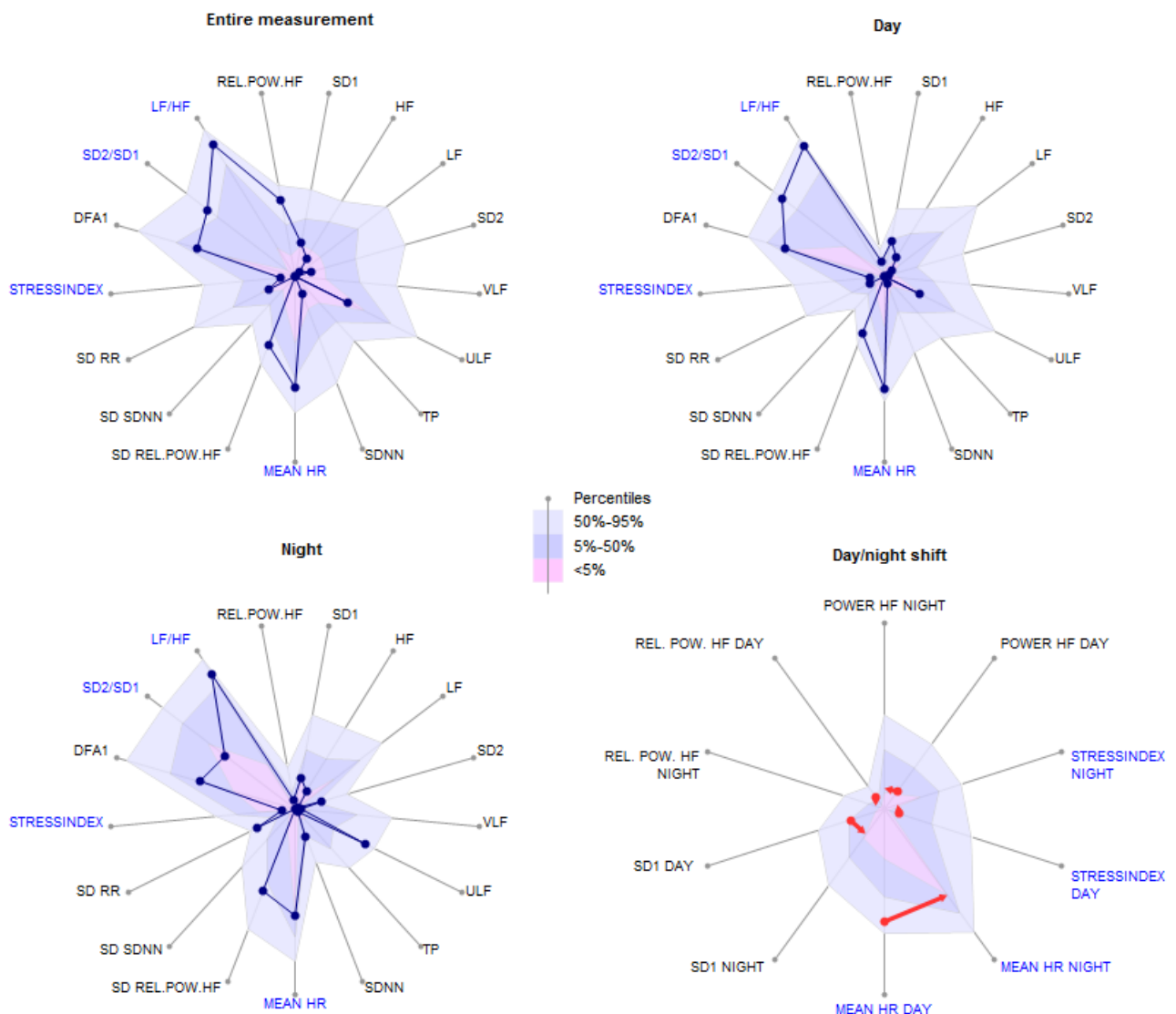


Figure: 74-year-old CHD patient with poor nighttime recovery

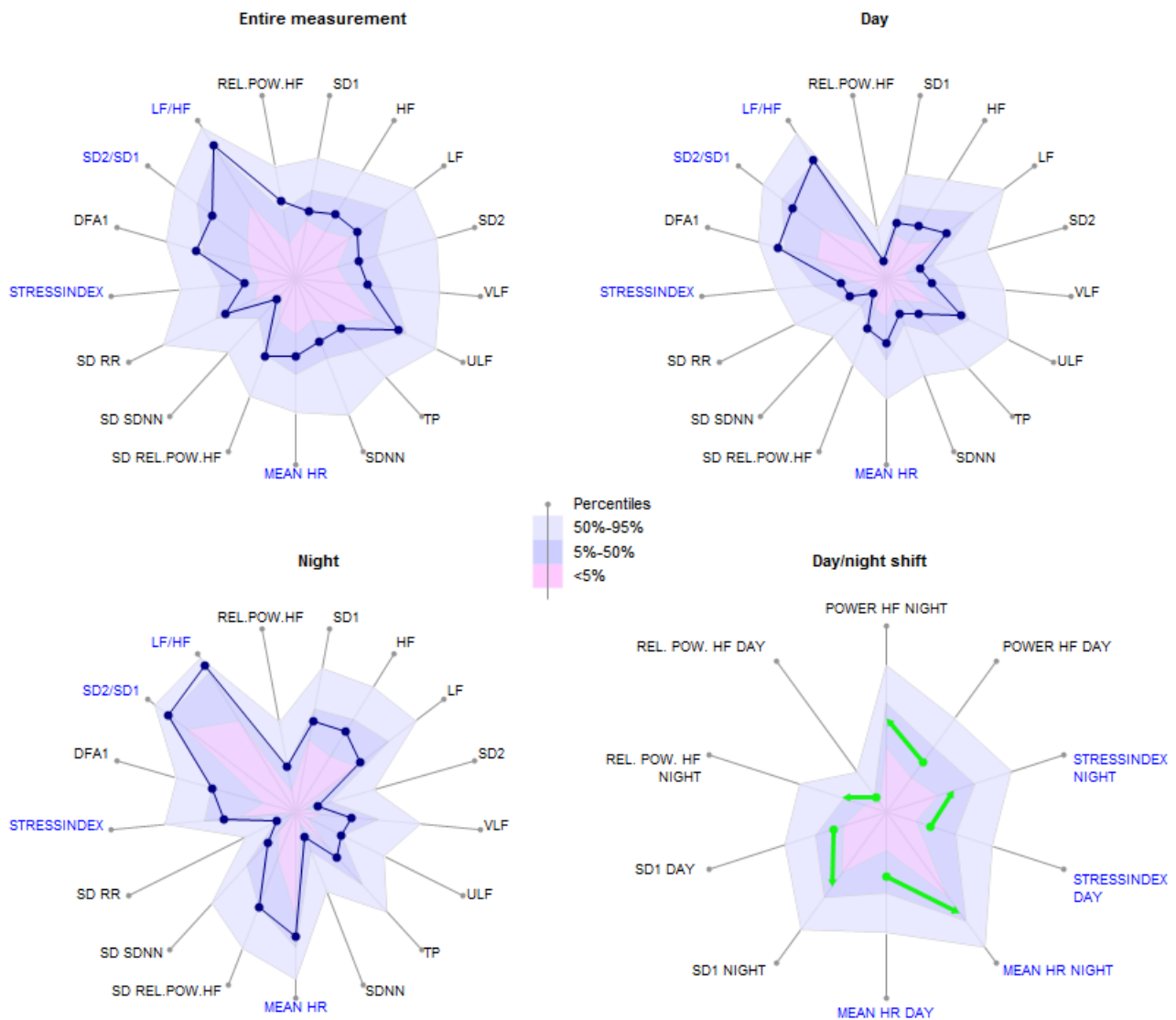
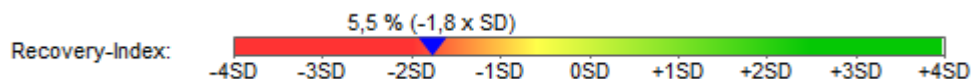


Figure: 43-year-old with average neurovegetative regulation, normal finding.

Assessment of nocturnal recovery

The Spiderweb Diagram "Day / Night Shift" displays the average daily value for some selected parameters and the corresponding night value immediately next to it (counterclockwise). The corresponding percentiles are also shown. An arrow colored after the traffic light principle shows the change of day and night. If the absolute HRV value deteriorates, a red arrow is displayed. If the absolute HRV value and the percentiles improve, a green arrow will be displayed. If the absolute HRV value improves, but the night value ranking falls by more than 5%, the arrow is yellow (not optimal regeneration). The average relative improvement in HRV parameters is also calculated as a numerical value and is available as a recovery index on the Sleep graph:



Picture: Recovery index of a patient with a sleep disorder.

The recovery index expresses the average percentage improvement in important HRV parameters during the night compared to the day. The numerical value in parentheses indicates how the calculated recovery index compares to a standard sample. On average, the subjects in the study on healthy subjects achieved a recovery index of 31% with a standard deviation of 14%. In the above example, the recovery index is almost two standard deviations below the mean, so it is a well below average recovery.

Note: The Recovery Index quantifies the difference in HRV from day to night. Are there hardly any stresses during the day, e.g. due to bed rest or long lay periods, the recovery index may be low, although the parasympathetic tone is high at night. Therefore, to interpret the recovery, it is recommended that you look at the daily stress load and parasympathetic and sympathetic activity using the following performance indexes.

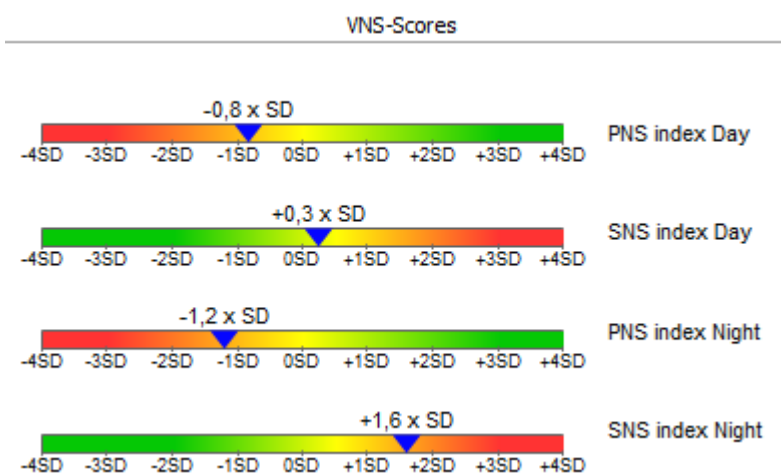
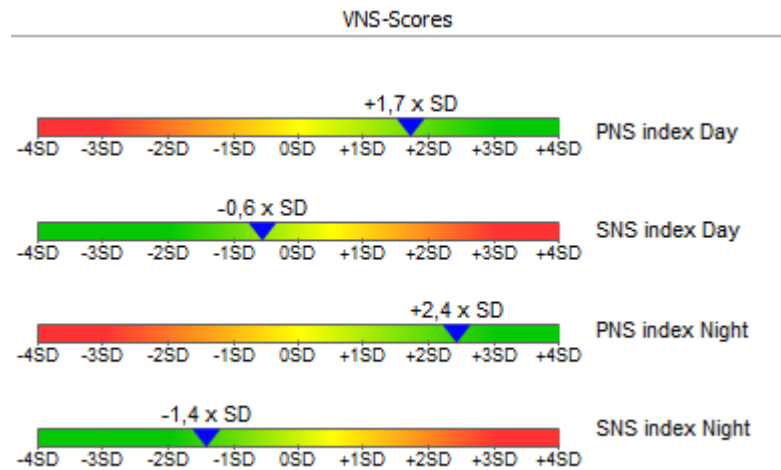
Specific performance indexes for the sympathetic and parasympathetic nervous system

To assess the vegetative balance, the HRV scanner calculates performance indices for day and night.

- PNS Index, (Parasympathetic Index): Based on parameters whose absolute value increases with increasing parasympathetic activity: mean RR distance, PNN50, Power HF, Rel. Power HF, SD1
- SNS index, (Sympathetic index): Based on parameters whose absolute value increases with increasing sympathetic activity: mean heart rate, SD2 / SD1 ratio, stress index.

To calculate the respective index, an age- and variance-corrected Z value is determined for each parameter and converted into a standard normal distribution by Z transformation. The resulting index is the average of the Z-transformed values of the individual parameters.

Accordingly, a PNS index of $+1 \times \text{SD}$ means that the underlying parasympathetic parameters are, on average, one standard deviation above the average of a normal age group of the same age.



„Functional HRV Age“ and „Premature Aging (PMA)“

Age is one of the most important risk factors for cardiovascular diseases. As we age, cardiovascular events such as heart attack are more likely to occur. For this reason, the age is usually included as an important factor in the calculation of risk scores, see, for example, the Procam score. Reduced HRV may also indicate an increased cardiovascular risk.

Interesting is the joint consideration of HRV and age: With increasing age, the neurovegetative regulatory capacity and thus the HRV decreases, see figure:

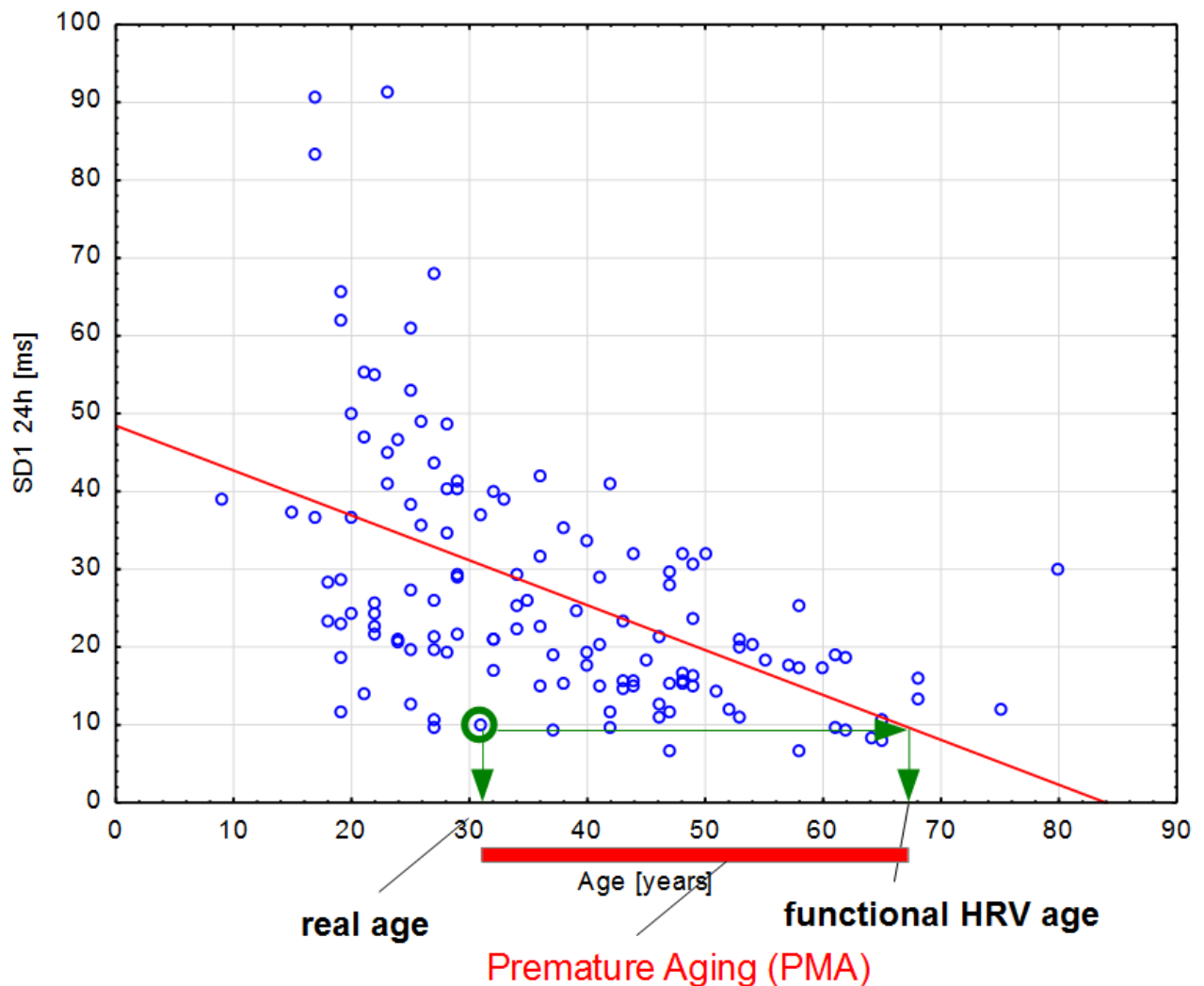


Figure: Decrease in HRV using the example of SD1 with increasing age in a standard collective of healthy volunteers.

For many HRV parameters the age of the subjects is even the most important factor for the differences in the HRV between different subjects (inter-individual variance). Low HRV values below the regression line can be interpreted in this context as premature aging (PMA) of the neurovegetative system. The extent of premature aging can be quantified by the functional HRV age (age value resulting from the intersection of the HRV value with the 50% percentile of the normal population). The difference of the functional HRV age from the actual age is the PMA Value and expresses how many years the neurovegetative system is older than the actual age. Negative PMA values indicate that the neurovegetative system is younger than his or her chronological age.

The functional HRV age and PMA value are calculated in the HRV scanner for 52 HRV parameters, which have in common that they correlate highly with age ($r > 0.5$). The resulting functional HRV age is the median of the 52 individual values.

Note: In the short-term HRV analysis, the functional HRV age is also calculated and reported as "biol. HRV age". The key difference in the calculation is the consideration of the heart rate in determining the functional HRV age in the new 24-hour analysis. It has been clearly shown in our examinations that the HRV not only depends on the age, but also strongly on the heart rate. In turn, age and heart rate are only weakly correlated, i.e. largely independent of each other. (Getting older, the heart rate usually decreases slightly). If the heart rate is not taken into account HRV is overestimated at low heart rates and underestimated at high heart rates. For this reason, we recommend using the more modern concept of functional HRV age in 24h analysis and less the biol. HRV age of the short-term analysis. In the latter case, the heart rate should always be taken into account in the interpretation.

However, the required heart rate correction for determining the functional HRV age reaches its limits in the case of strongly deviating heart rates. In such a case, the functional HRV age should be interpreted with restraint. However, the HRV-Scanner issues a warning message if it detects very high or very low heart rates.

To interpret the functional HRV age, the corresponding PMA diagram provides valuable information.

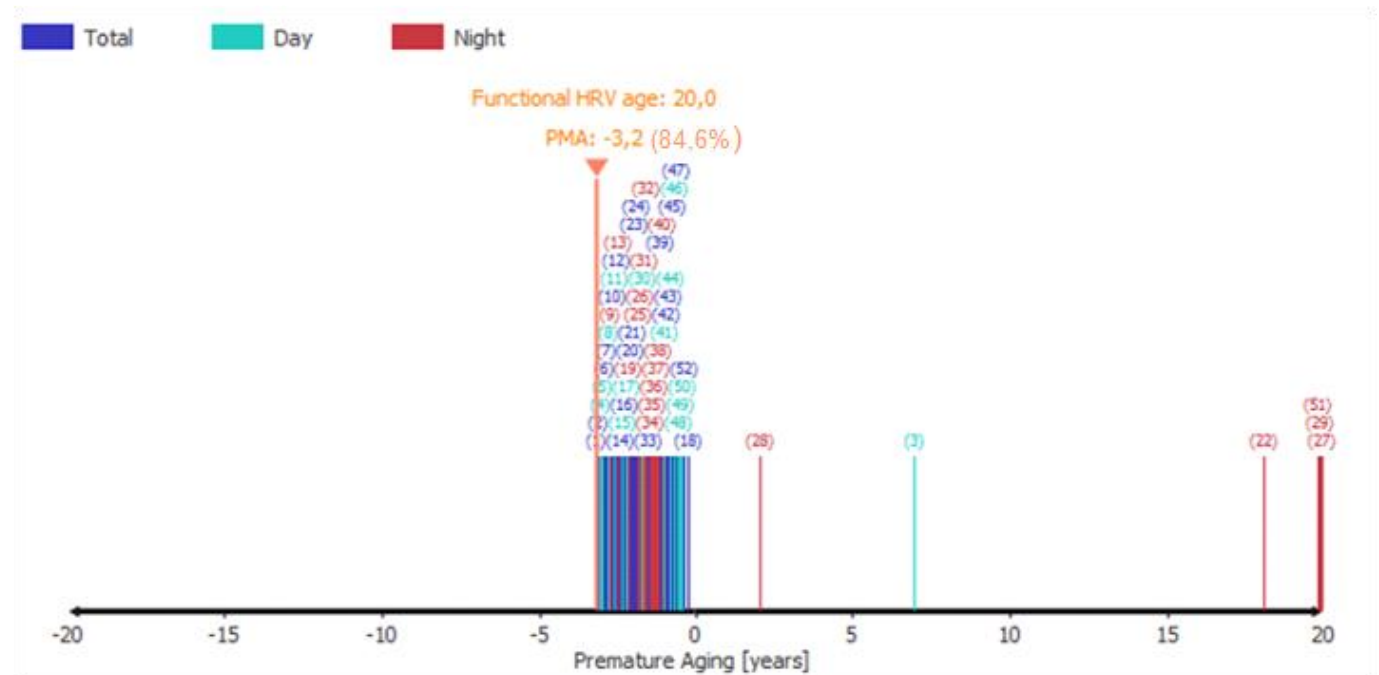


Figure: PMA diagram of a 23-year-old competitive athlete. The numbers in parentheses above the marks indicate the ID of each parameter. The percentage next to the parenthesized PMA value indicates the percentage of parameters that support the current PMA value.

Each vertical mark corresponds to the PMA value of a single HRV parameter. The color indicates whether it is a parameter of the entire measurement, only the daily values or only the night values. It can be seen in the example at first glance that almost all parameters have a negative PMA value, i.e. the resulting functional HRV age is lower than it corresponds to the actual age. It is therefore an above-average powerful neurovegetative control system.

Note:

The functional HRV age is limited to a range between 20-85 years. If, for example, an HRV age of 10 years results internally, the value is corrected to 20 years and output. For this reason there are no PMA values in the above example of a 23-year-old younger than -3 years.

For better readability of the diagram, marking lines with the same PMA value are not drawn one above the other but drawn next to the previous line. This creates the impression of a broad bar and it becomes intuitively visible in which area most PMA values lie.

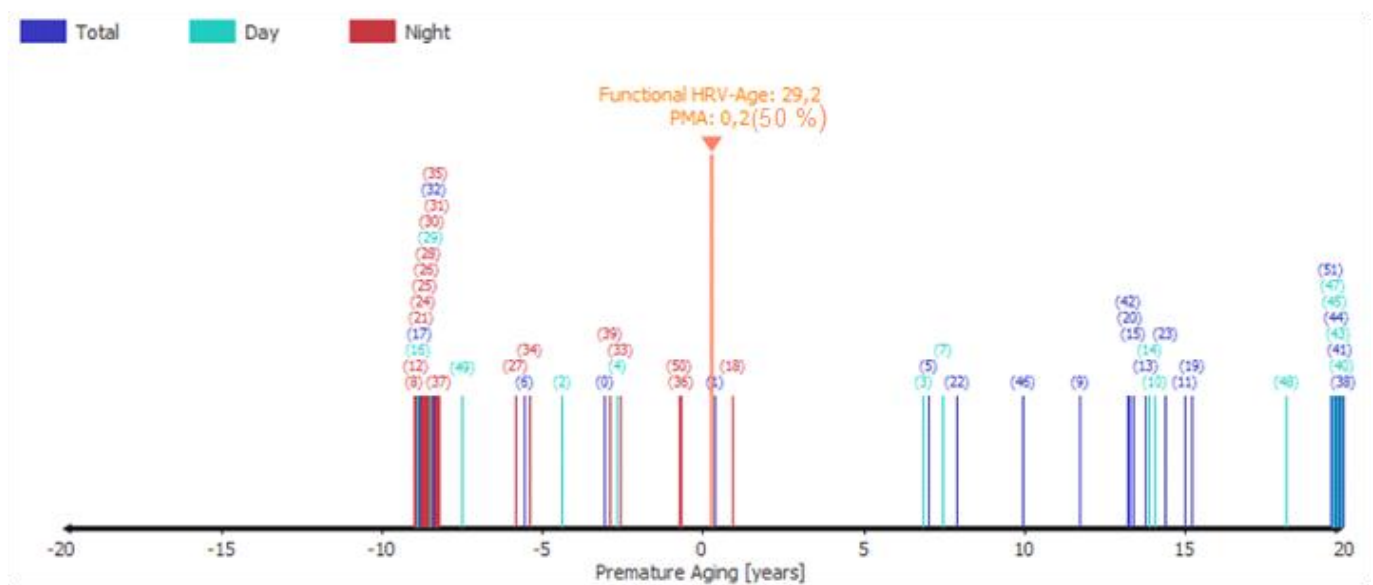


Figure: PMA chart of a 29-year-old subject. The tag values indicate a significantly higher premature aging than the night values. This is an indication that neurovegetative regulation is limited during the day. Possible causes are, for example, excessive stress during the day.

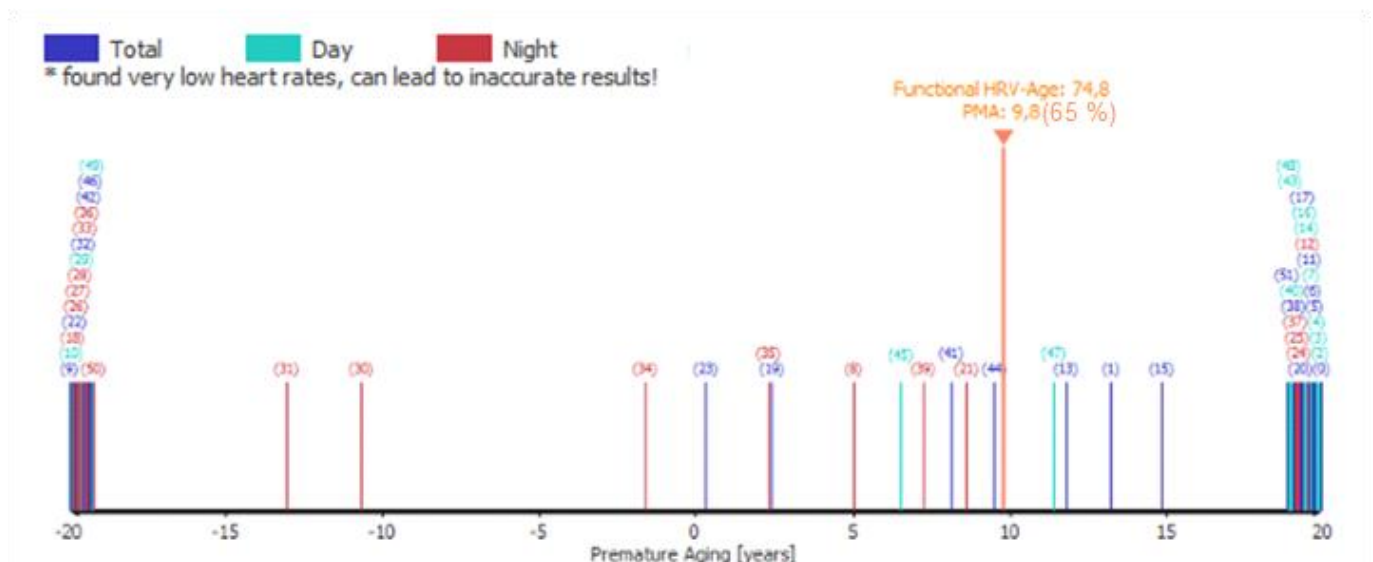


Figure: PMA diagram of a 65-year-old subject. The single PMA values split into two opposing clusters. At the same time, a heart rate alert is issued. The proportion of conspicuous parameters is around 40% for day and night, which is decidedly high. Such an HRV measurement is valid only under reserve. The PMA value and the functional HRV age should not be used.

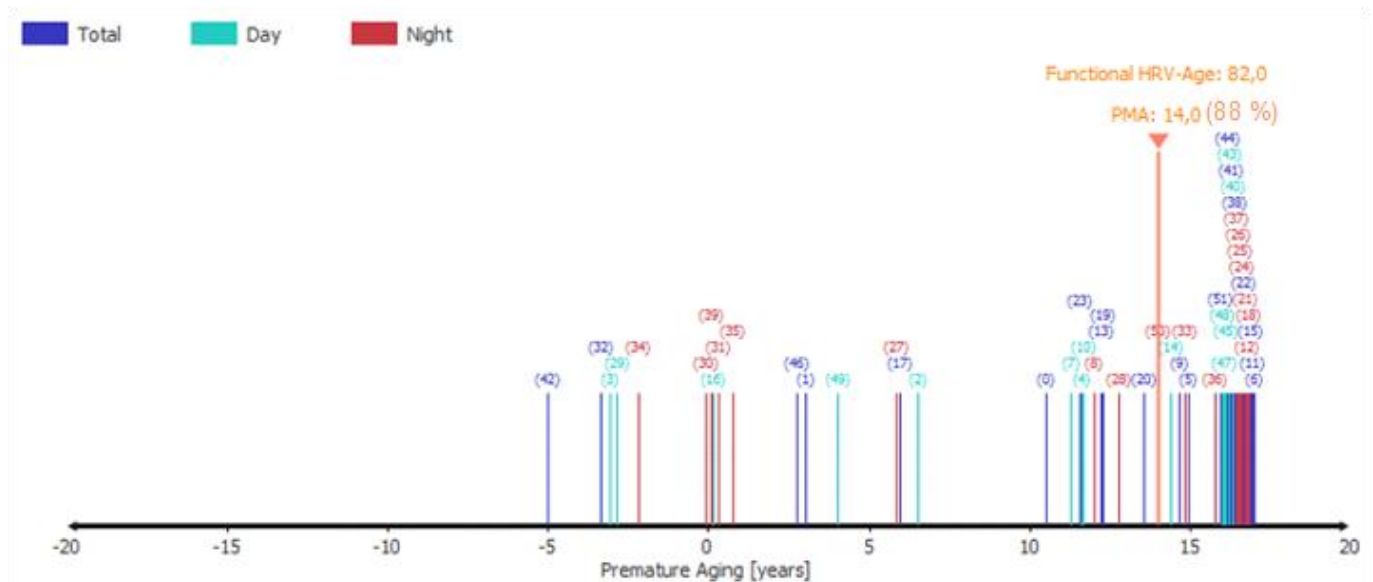


Figure: PMA diagram of a 68-year-old CHD patient. Almost all parameters have a positive PMA value. The functional HRV age is 14 years over the actual age.

Functional HRV age as a risk

We investigated whether cardiovascular disease can be distinguished from healthy individuals based on the functional HRV age. For this purpose, the data of a healthy control group ($n = 140$) were compared with those of a patient group with angiographically confirmed CHD ($n = 191$). For all calculated HRV parameters including "functional HRV age", the effect size (Cohen's d) of the group difference was calculated. The greater the difference between two groups relative to a particular parameter, the greater its effect size. To assess whether an effect size is large or small, see the table:

Effect size	d	Reference
Very small	0.01	Sawilowsky, 2009
Small	0.20	Cohen, 1988
Medium	0.50	Cohen, 1988
Large	0.80	Cohen, 1988
Very large	1.20	Sawilowsky, 2009
Huge	2.0	Sawilowsky, 2009

(https://en.wikipedia.org/wiki/Effect_size#Cohen's_d)

Of all the 311 HRV parameters studied, the "functional HRV age" with an effect size of 1.896 was the parameter with the greatest effect size and thus the best discrimination between patients with CHD and healthy subjects. Typical HRV parameters such as SDNN ($d: 0.872$), SD1 ($d: 0.654$) or Power HF ($d: 0.881$) had significantly lower effect sizes.

The top rank of effect size for "functional HRV age" persisted when CHD patients were separately enrolled in the group without beta blocker ($d: 1.571$) and beta blocker ($d: 1.972$).

Conclusion: Age is a risk for cardiovascular disease, as well as a limited neurovegetative regulation. The "functional HRV age" is a virtual age value, which basically makes a description of the neurovegetative regulation in the sense of: "The neurovegetative regulation corresponds to that of an xx year old".

The higher the "functional HRV age", the higher the cardiovascular risk. Due to the heart rate correction in the calculation of the "functional HRV age", the latter is independent of the heart rate and can even be calculated in patients undergoing beta blocker therapy.

Sleep

Sleep is a highly active process in which various degrees of activation are cycled. Deep sleep phases alternate with light sleep phases and phases of high, wakeful EEG activity with rapid eye movements (REM). During normal nighttime sleep, the influence of the parasympathetic nervous system predominates, with reduced sympathetic tone. In the REM phases, the sympathetic tone increases.

A restful sleep is essential to maintain good health. Insufficient sleep or sleep disturbances can cause serious health problems if they last longer. A well-known example is the increase in cardiovascular risk when sleep apnea occurs.

There are many problems falling asleep and staying asleep, as a result of which the quality of sleep is reduced. The natural sequence of the various sleep phases is then usually disturbed. This also has an effect on the autonomic nervous system: the predominance of the parasympathetic nervous system, which is important for recovery, is diminished or completely absent.

The diagnosis of sleep disorders is complex and usually requires the registration of many different physiological parameters in the sleep laboratory (polysomnography). The HRV analysis cannot replace this, however, the HRV analysis can sometimes provide valuable information on the presence of a sleep disorder: For example, there are characteristic changes in the frequent obstructive sleep apnea:



Image: Characteristic patterns of respiration (derived from ECG) and heart rate with pronounced, polysomnographically confirmed sleep apnea. There are 1-2 apnea phases per minute, accompanied by larger heart rate oscillations and a spindle-shaped breathing pattern.

The HRV scanner searches for respiratory, heart rate, and HRV patterns that are characteristic of sleep apnea. The strength and frequency of these patterns are quantified in the form of an "OSA score". The OSA score was developed using the SHHS study, which comprises several thousand polysomnographic datasets. (Quan SF, Howard BV, Iber C, Kiley JP, Nieto FJ, O'Connor GT, Rapoport DM, Redline S, Robbins J, Samet JM, PW, The Sleep Heart Health Study: design, rationale, and methods 1997 Dec; 20 (12): 1077-85. PubMed PMID: 9493915.)

For validation, the algorithm was tested on the datasets of the freely available OSA database. (T Penzel, GB Moody, RG Mark, AL Goldberger, JH Peter, The Apnea ECG Database, Computers in Cardiology 2000, 27: 255-258.) The correlation of the HRV scanner OSA score with the polysomnographically determined AHI (apnea Hypopnea index) was 0.83. Sensitivity and specificity to detect a moderate severity OSA (AHI >= 15) were 95% and 96%, respectively. High OSA scores in the HRV scanner can therefore be considered an indication of a possible sleep apnea.

However, a high OSA score does not automatically mean that obstructive sleep apnea is certain. Incidentally, this applies to all screening examinations; a positive test result is not necessarily synonymous with illness, even if that is often interpreted that way. The pretest probability (prevalence) also plays a major role:

For example, breast cancer screening has a sensitivity of about 90% and a specificity of about 94%. With a prevalence of breast cancer of 0.8%, this results in a positive predictive value (posttest probability) of about

10% for breast cancer with a positive mammogram finding. That is, only one in ten women with a positive mammographic finding actually has breast cancer. (Kerlikowske K, Grady D, Barclay J, Sickles EA, Serious V. Likelihood Ratios for Modern Screening Mammography.) JAMA, 1996 Jul 3; 276 (1): 39-43.) (Depending on the underlying study, this value is slightly larger or smaller, but always on a similar scale).

The critical size of a diagnostic test is the likelihood ratio (LR) of the test because LR and prevalence can be used to calculate the probability of post testing, i.e. the likelihood that a positive test result will actually be present. For more information on the LR see also:

https://en.wikipedia.org/wiki/Likelihood_ratios_in_diagnostic_testing

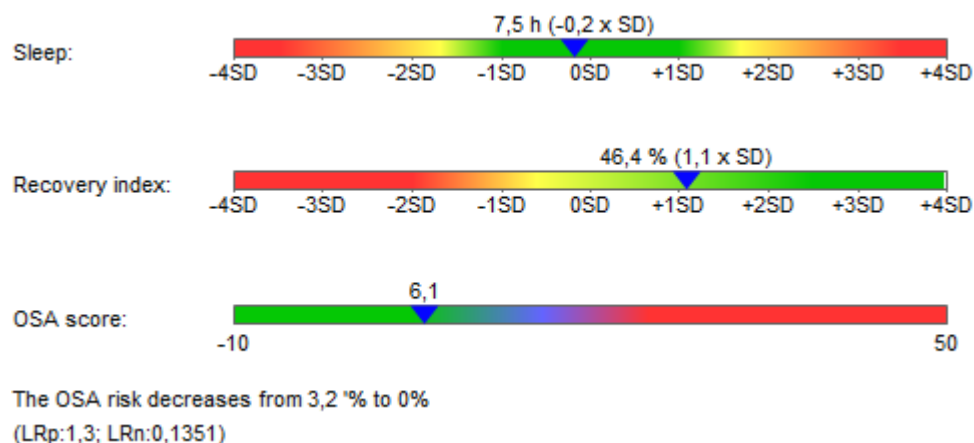
In short, the positive likelihood ratio (LRp) indicates how much more often a sufferer receives a positive test than a healthy one. The negative likelihood ratio (LRn) indicates how much more frequently a patient receives a negative test result than a healthy one.

Incidentally, the LR for mammography screening is about 14, i. Positive mammography is 14 times more common in breast cancer patients than in women without breast cancer.

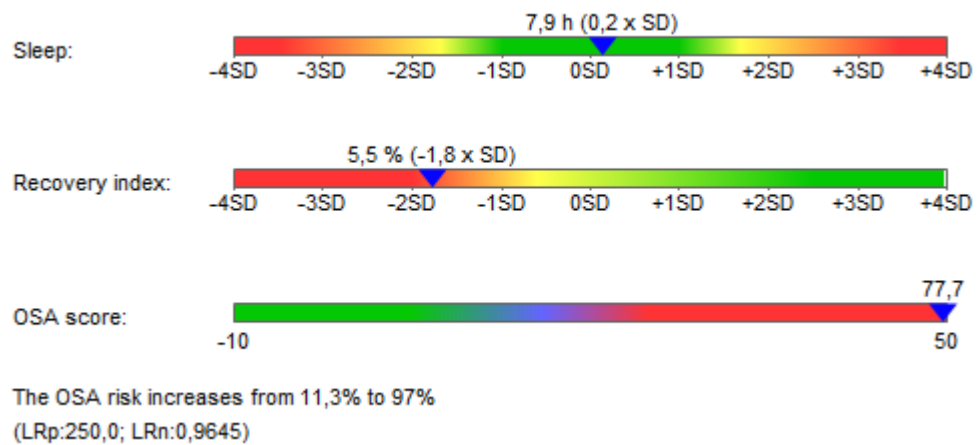
The HRV scanner calculates the associated likelihood ratios (LRs) for each OSA score. The prevalence table and LRs are also used to calculate the likelihood (posttest probability, positive predictive value) of sleep apnea (Punjabi NM., The epidemiology of adult obstructive sleep apnea, Proc Am Thorac Soc. 2008 Feb 15; 5 (5). 2): 136-43 doi: 10.1513 / pats.200709-155MG.).

	20-44 Years	45-64 Years	>64 Years
Men	3,2	11,3	18,1
Women	0,6	2,0	7.0

Table: OSA prevalence



Picture: Sleep parameters of a healthy subject. A low OSA score lowers the probability of OSA



Picture: Sleep parameters of a patient with polysomnographically confirmed OSA.

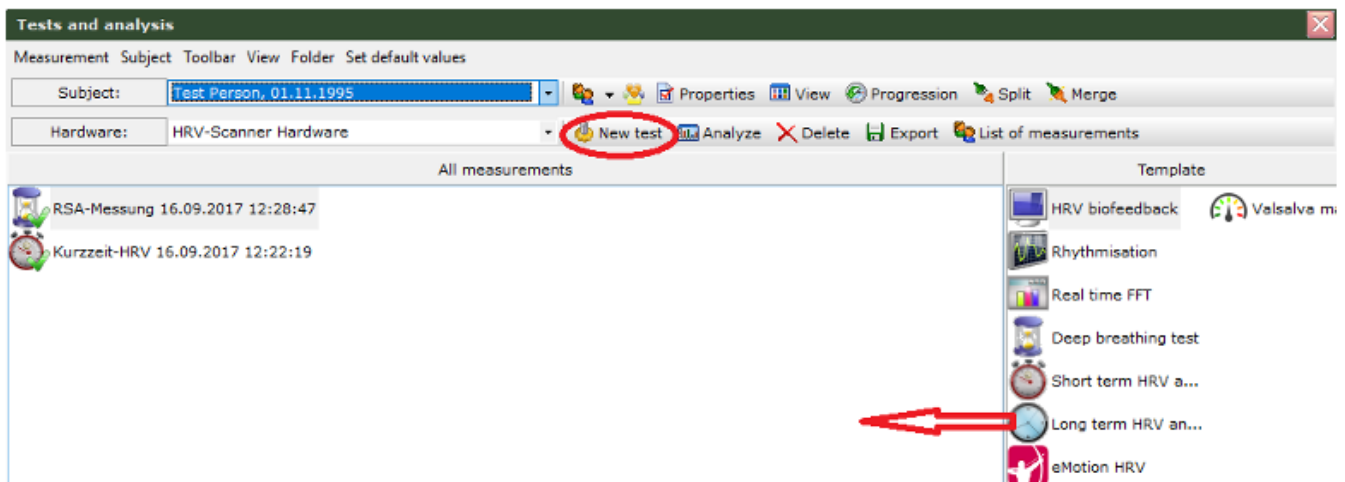
Note: HRV analysis cannot replace the diagnosis of OSA using polysomnography. However, high OSA scores in the HRV scanner, especially in conjunction with clinical symptoms such as increased daytime sleepiness, should make one think of sleep apnea.

Working with templates in the HRV-Scanner

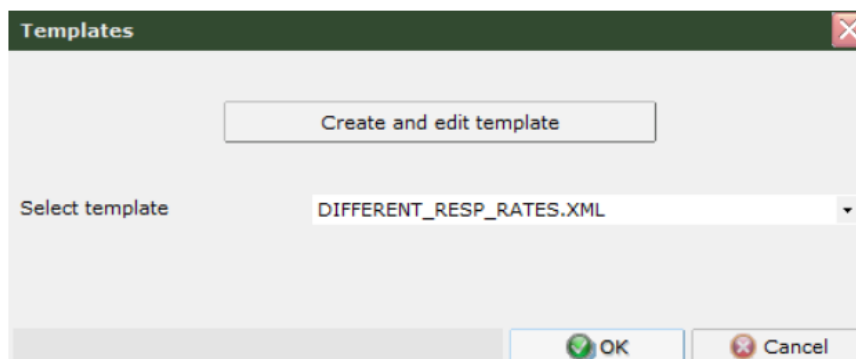
Templates extend the analysis options of the HRV-Scanners. Instead of a maximum of three phases it is now possible to define and analyze up to 30 different parts for each measurement.

Creating Templates

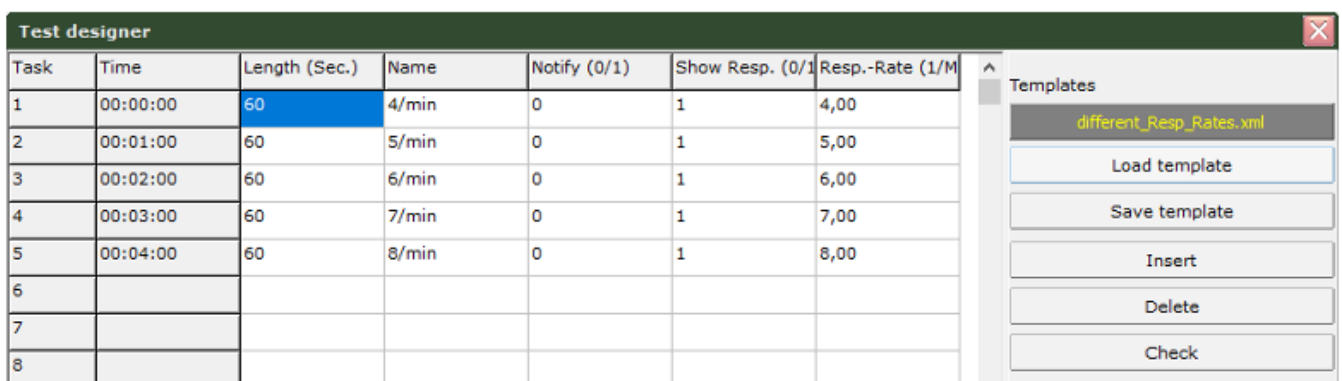
In order to create a new template start a new long term HRV test as usual.



A window will appear where you can either create and edit a template or select a template.

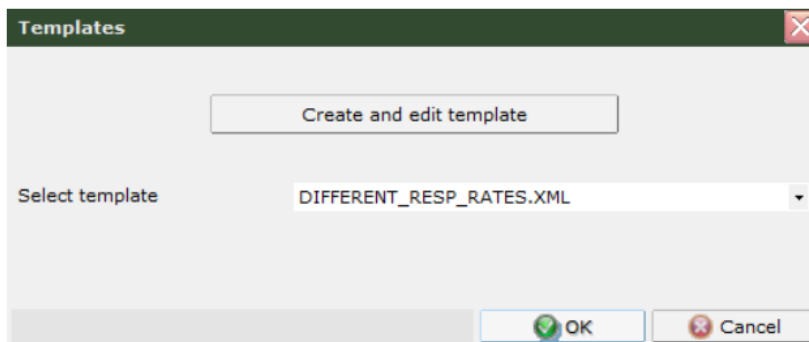


Press on 'Create and edit template' in order to start the Test-Designer.



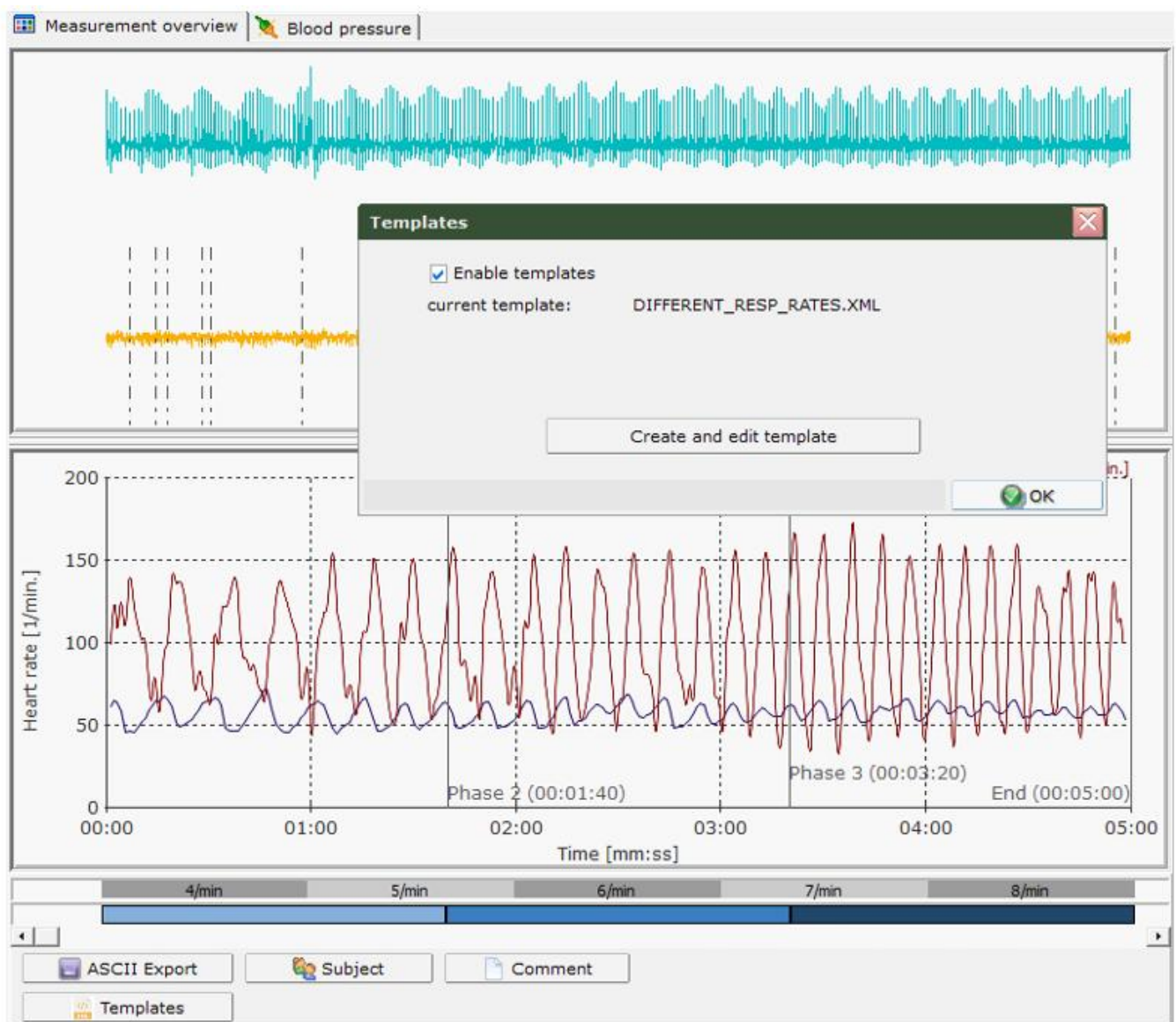
Define the desired number of tasks. By means of the 'Notify' field you can activate a message box, which occurs several seconds before the related tasks starts. The field 'Show Resp.' determines whether a breathing aid is displayed or not. In 'Resp-Rate' you can specify the corresponding respiration frequency. Save the template after completion. Please notice that it has to be saved in the folder 'XMLTemplate'.

Choose the desired template and press OK in order to start the measurement.



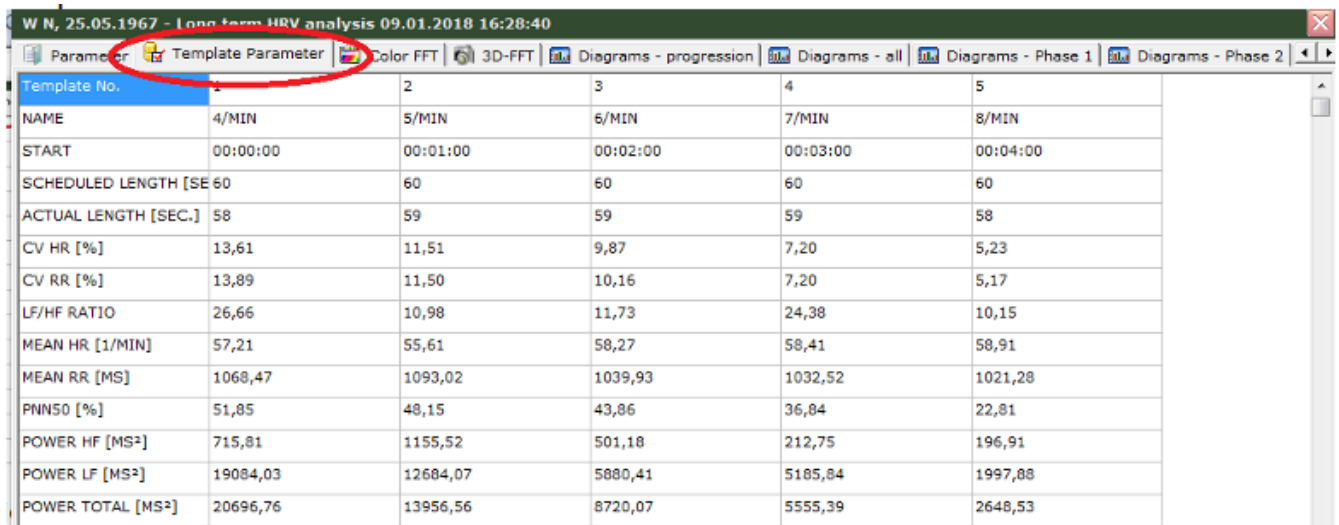
Analysis with Templates

Every recorded measurement can additionally be analyzed with templates. In case of a long term measurement, the corresponding template will be automatically loaded. For all other measurements templates can be added or created. If a template is active the respective tasks of the template are depicted above the phase bars.



Please note that all changes on the templates of a certain measurement are saved in the corresponding data file and do not affect other templates or measurements!

For every task of the template several parameters are calculated and shown on a spreadsheet.

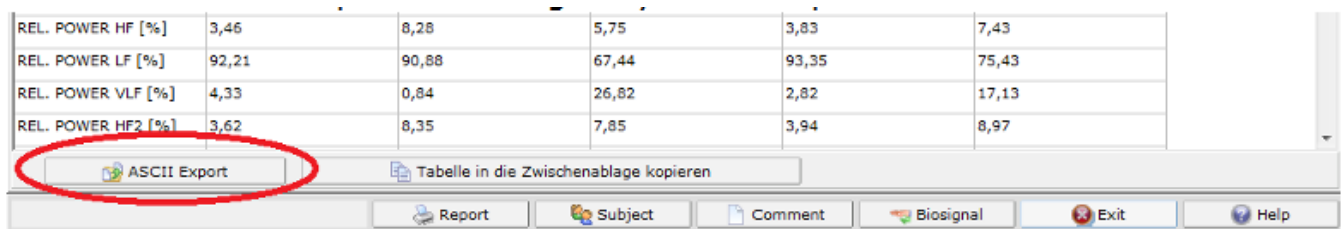


Template No.	2	3	4	5
NAME	4/MIN	5/MIN	7/MIN	8/MIN
START	00:00:00	00:01:00	00:02:00	00:03:00
SCHEDULED LENGTH [SE 60]	60	60	60	60
ACTUAL LENGTH [SEC.]	58	59	59	58
CV HR [%]	13,61	11,51	9,87	7,20
CV RR [%]	13,89	11,50	10,16	7,20
LF/HF RATIO	26,66	10,98	11,73	24,38
MEAN HR [1/MIN]	57,21	55,61	58,27	58,41
MEAN RR [MS]	1068,47	1093,02	1039,93	1032,52
PNN50 [%]	51,85	48,15	43,86	36,84
POWER HF [MS ²]	715,81	1155,52	501,18	212,75
POWER LF [MS ²]	19084,03	12684,07	5880,41	5185,84
POWER TOTAL [MS ²]	20696,76	13956,56	8720,07	5555,39

Parameters that are not calculated because for example the task duration was too short are being displayed with the numeric code '999999'.

ST.DEV. [1/MIN]	7,79	6,40	5,75	4,21	3,08
STRESSINDEX	28,02	21,79	31,75	49,12	78,33
LN(STRESSINDEX)	3,33	3,08	3,46	3,89	4,36
DFA1	999999	999999	999999	999999	999999
DFA2	999999	999999	999999	999999	999999
AUTOCORREL.	0,8417	0,8012	0,7657	0,7324	0,6801
SLOPE OF AUTOCORREL.	0,0088	-0,0098	-0,0187	0,0027	0,0190
RESP. RATE	4,3097	5,2373	6,1465	7,0049	8,1790

The table can be exported analogously to other parameter list in ASCII-Format.



REL. POWER HF [%]	3,46	8,28	5,75	3,83	7,43
REL. POWER LF [%]	92,21	90,88	67,44	93,35	75,43
REL. POWER VLF [%]	4,33	0,84	26,82	2,82	17,13
REL. POWER HF2 [%]	3,62	8,35	7,85	3,94	8,97

Notice:

The table contains a couple of new, experimental HRV parameter. The number of these parameter and their calculation basis may change in the future. Therefore, we reserve the right to change the number and the calculation basis of template parameter in future releases. If the template parameter are used in scientific studies, we recommend to contact BioSign in order to obtain more detailed information.

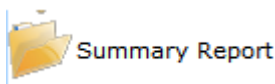
Summary Report

Performing a neuro-vegetative functional analysis usually involves the combination of several single functional tests, e.g. Short-term HRV, RSA, Supine / Standing (Schellong) and Valsalva maneuvers. The assessment of whether a neurovegetative disorder is present usually results from the overall view of all measurements results. With the HRV scanner, it is now possible to perform this overall evaluation automatically.

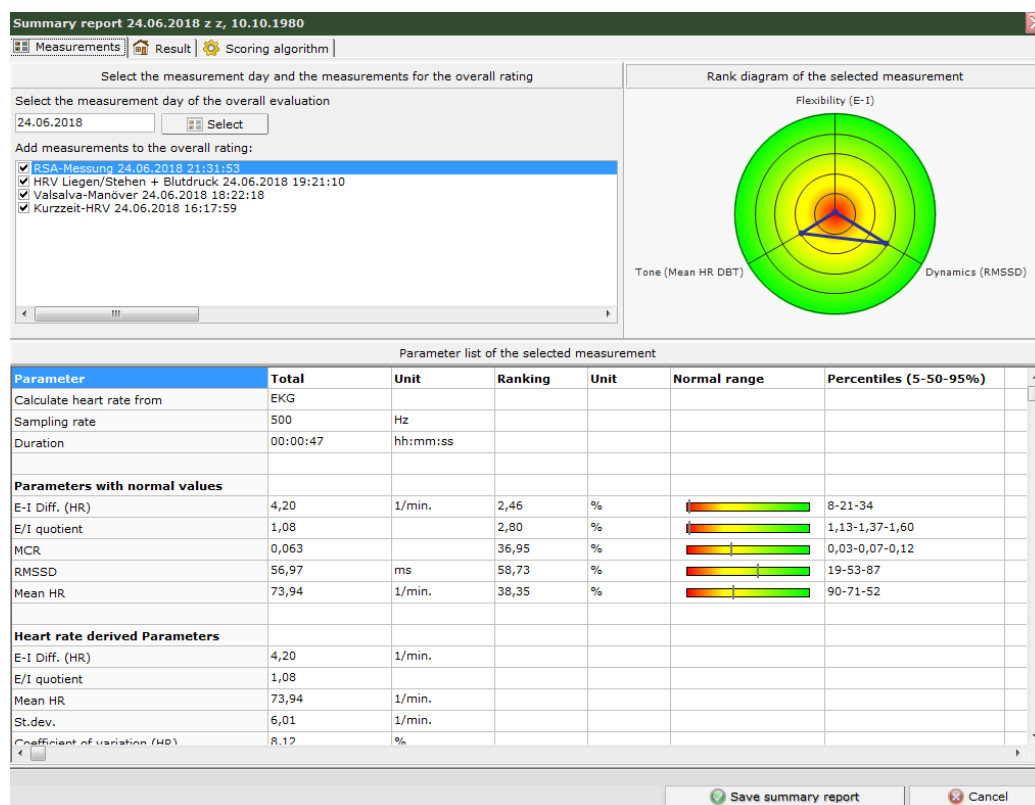
In order to create the overall rating, the individual measurements must be evaluated. The target parameters of the individual functional tests are weighted using a scoring system and summed up to a total score. The underlying scoring system is adjustable by the user and can be easily adapted to own requirements.

Creating a Summary Reports

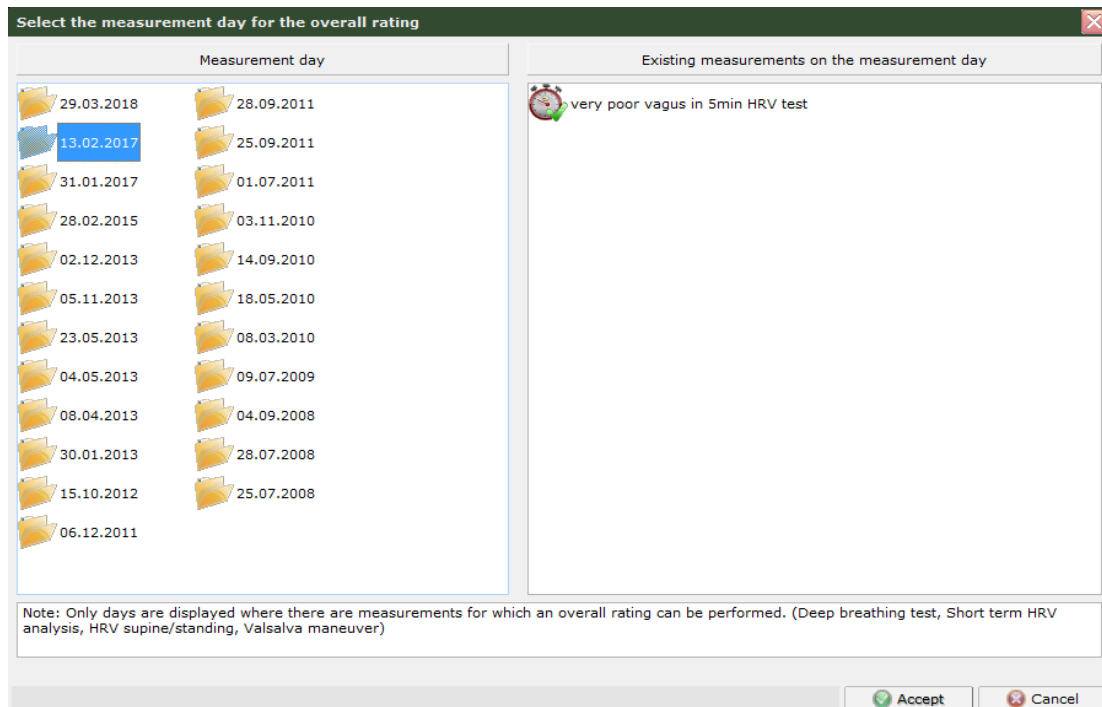
Creating a summary report is analogous to starting a new measurement.



Drag the summary report symbol with the mouse into the left window of the subject measurements. The overview window of the summary report shows the available measurements for the selected measurement day and the results of the currently selected measurement.

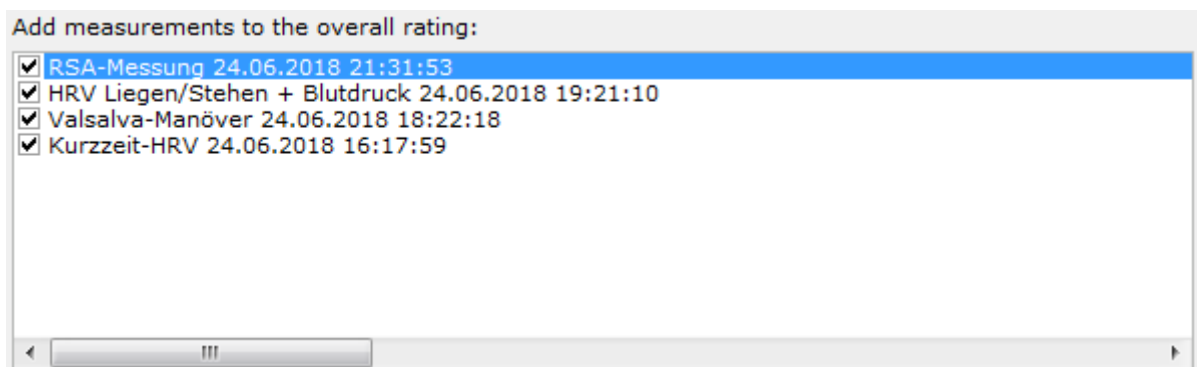


You can select the measurement day via a dialog. The summary report overtakes the date of the selected measurement day and is accordingly also sorted in the list of tests in the "Test and Analysis" window.



In the selection dialog for the measurement day, only days are displayed on which measurements are available, and for which a summary report can be generated (RSA measurement, short-term HRV, Supine / Standing HRV, Valsalva maneuver).

After selecting the measurement day you will see the available measurements in the list. Here you can select which measurements should be evaluated in the summary report.



Measurements that have not yet been evaluated, or in which there have been errors in the evaluation, cannot be used and must first be reworked.

Result

Summary report 24.06.2018 z z, 10.10.1980

Measurements
Result
Scoring algorithm

Overall rating

Note! During the evaluation 1 errors have occurred.

Achieved total score of all measurements (n = 6): 17/32 =53,13%

Rating: normal

* 0-30% auffällig; 30-50% grenzwertig; 50-101% normal

Scoring algorithm: test

Report

Results of the single measurements

Test	Type	Parameter	Value	Unit	Ranking[%]	Score[Pts.]	Total[Pts.]	Rating
RSA-Messung 24.06.2018 21:31:53	DBT	E-I	4,20	1/min.	2,46	0		
		RMSSD	56,97	ms	58,73	2		
		Mean HR DBT	73,94	1/min.	38,35	2	4/6	normal
HRV Liegen/Stehen + Blutdruck 24.06.2018 19:15	Short Term H	Coefficient of variation (R	6,05	%	28,82	2		
		SD1	22,52	ms	11,99	1		
		SD2	76,38	ms	38,40	2		
		Stress index	83,51	Pts.	40,68	2		
		Mean HR	64,75	1/min.	73,19	2	9/10	normal
HRV Liegen/Stehen + Blutdruck 24.06.2018 19:15	Ewing	30:15 Ratio	1,31		42,17	2	2/2	normal
HRV Liegen/Stehen + Blutdruck 24.06.2018 19:15	Blood pressur	Blood pressure change sy	-10,00	mmHg		ERROR		
		Blood pressure change di	-11,00	mmHg		0	0/2	auffällig
Valsalva-Manöver 24.06.2018 18:22:18	Max. score of	Valsalva Ranking	1,94		76,81	2	2/2	normal
Kurzzeit-HRV 24.06.2018 16:17:59	Short Term H	Coefficient of variation (R	0,66	%	1,91	0		
		SD1	1,61	ms	1,36	0		
		SD2	5,13	ms	1,62	0		
		Stress index	4641,50	Pts.	0,39	0		
		Mean HR	103,54	1/min.	0,37	0	0/10	auffällig

* "ERROR" means no fitting scoring algorithm was found for this parameter! Adjust the settings.

As a result you can see the overall rating of the measurement day in the upper panel, including the individual test with the respective parameters. "ERROR" means that no scope was found for a parameter in the scoring conditions, and thus there is an inconsistency in the scoring system. Correct the calculation algorithm in this case.

The following explains how to implement your own scoring algorithm.

Definition of the scoring algorithm of a summary report

Step 1: Selection of the individual parameters

Measurements | Result | **Scoring algorithm**

Bezeichnung: default

Overall rating | **Deep breathing test** | Short term HRV analysis | HRV supine/standing Ewing | HRV supine/standing Blood pressure | Valsalva maneuver

☒ **Tone (Mean HR DBT)**
if Ranking >= 0 and Ranking < 10 then point value = 0
if Ranking >= 10 and Ranking < 15 then point value = 1
if Ranking >= 15 and Ranking < 101 then point value = 2
Define point values

☒ **Flexibility (E-I)**
if Ranking >= 0 and Ranking < 10 then point value = 0
if Ranking >= 10 and Ranking < 15 then point value = 1
if Ranking >= 15 and Ranking < 101 then point value = 2
Define point values

☒ **Dynamics (RMSSD)**
if Ranking >= 0 and Ranking < 10 then point value = 0
if Ranking >= 10 and Ranking < 15 then point value = 1
if Ranking >= 15 and Ranking < 101 then point value = 2
Define point values

For each test, specific individual parameters are available. Among these you can select which parameters should be included in the evaluation.

Step 2: Defining the evaluation criteria for each parameter (defining scores)

Edit parameter conditions: Tone (Mean HR DBT)

if Ranking >= 0 and Ranking < 10 then point value = 0
if Ranking >= 10 and Ranking < 15 then point value = 1
if Ranking >= 15 and Ranking < 101 then point value = 2

Add a new condition | Delete a selected condition

Edit selected condition

if Ranking >= 0 and Ranking < 10 then point value = 0
* Ranking parameter (range 0% - 100%)

Accept | Cancel

The evaluation of the individual parameters is carried out by conditions and the allocation of scores. When defining the conditions, consider whether it is a relative rank parameter (percentile) with the unique range 0-100% or an absolute parameter (for example, blood pressure change) with its individual range. The individual conditions must be defined in such a way that the possible value range is completely covered. Please note that in case of blood pressure changes positive values (blood pressure rise) and negative values (blood pressure drop) can occur.


Step 3: Evaluation criteria for a single test

Depending on the results of the parameter evaluation, an evaluation is made for the individual test, so that each test receives a sum score.

Overall rating of the single measurement

Overall result of the test is "auffällig" and he gets a score of 0 if the total score of the test is ≥ 0 and < 2
Overall result of the test is "grenzwertig" and he gets a score of 1 if the total score of the test is ≥ 2 and < 3
Overall result of the test is "normal" and he gets a score of 2 if the total score of the test is ≥ 3 and < 7


Max. score of this test: 6


 Define rating and scores

The score of the individual test and the corresponding conclusion is defined from the individual parameters. The complete range of values from 0 points to the maximum achievable total score of a single test should be covered in the conditions.

Edit single test conditions: Short term HRV analysis

Overall result of the test is "auffällig" and he gets a score of 0 if the total score of the test is ≥ 0 and < 3
Overall result of the test is "grenzwertig" and he gets a score of 1 if the total score of the test is ≥ 3 and < 5
Overall result of the test is "normal" and he gets a score of 2 if the total score of the test is ≥ 5 and < 11

 Add a new condition

 Delete a selected condition



Edit selected condition

Overall result of the test is
auffällig

and he gets a score of
0


if the total score of the test is \geq
0

and $<$
3

 Accept  Cancel

Step 4: Evaluation of the complete functional analysis

Overall result is "auffällig" if total score of all tests $\geq 0\%$ and $< 30\%$ % of the possible total score
Overall result is "grenzwertig" if total score of all tests $\geq 30\%$ and $< 50\%$ % of the possible total score
Overall result is "normal" if total score of all tests $\geq 50\%$ and $< 101\%$ % of the possible total score

 Define rating and percentages

The evaluation of a complete function analysis is based on the ratio of the achieved score to the maximum achievable score.

Edit overall rating conditions

Overall result is "auffällig" if total score of all tests > = 0% and < 30% % of the possible total score
 Overall result is "grenzwertig" if total score of all tests > = 30% and < 50% % of the possible total score
 Overall result is "normal" if total score of all tests > = 50% and < 101% % of the possible total score

Add a new condition Delete a selected condition

Edit selected condition

Overall result is

if total score of all tests > =
 %

and <
 % of the possible total score

Accept Cancel

You can adjust the percentage score for each conclusion separately.

Import Options

ASCII

Import measurement in the form of heart rate or RR distance lists into the HRV-Scanner.

ASCII biosignals

Import measurements in the form of biosignal lists (ECG voltage curve in mV) into the HRV-Scanner.

EDF - European Data Format

Import of data in EDF format. E.g. Import of data from the measurement memory of Faros 180.

eMotion HRV

Long-term measurements with the eMotion HRV recorder.

Polar

Import of measurements from Polar watches (HRM files) already transferred to the PC.

Suunto

Import of measurements from the Suunto Memory Belt already transferred to the PC.



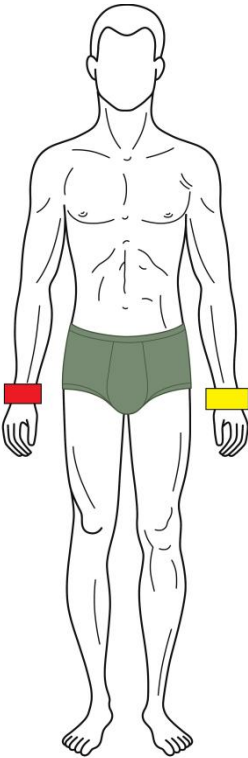
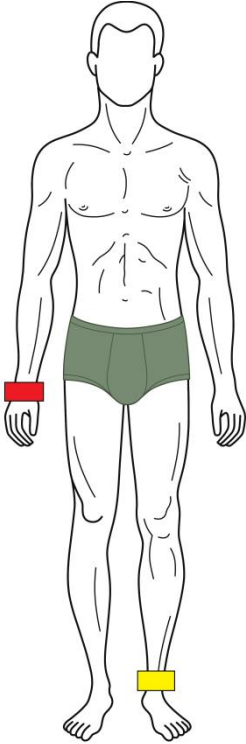
SRM long term measurement

Import the measurement data from the SRM recorder

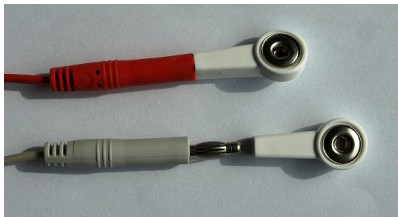
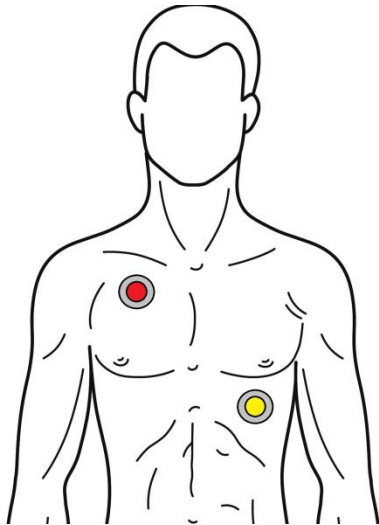
Possibilities of ECG derivation

Derivation of a 1-channel ECG with clamp electrodes

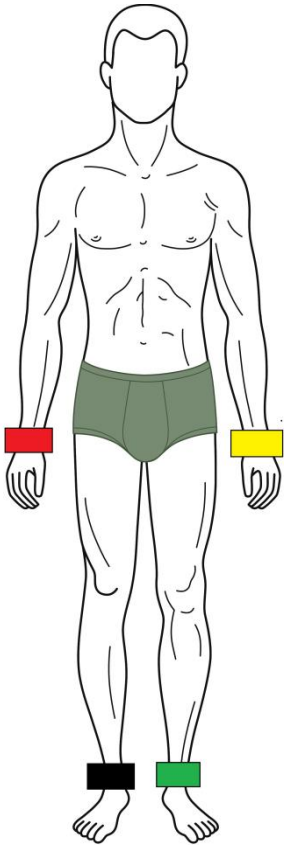
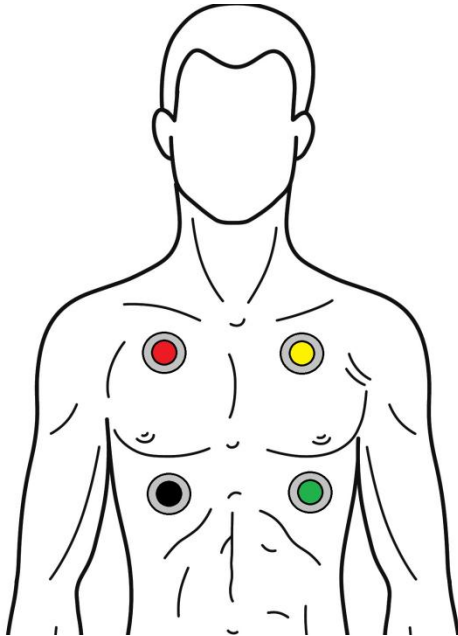
Preparation: connect the clamp electrodes with the ecg cable

Hardware standard (2-wire ECG cable, banana plug)	Hardware plus (4-wire ECG cable, electrode clip)
	
<p>1) Derivation of right arm against left arm</p> 	<p>2) Derivation of right arm against left foot</p> 
<p>This type of derivation works in 98% of cases. Exception would be e.g. an ECG in which the R-wave and the T-wave are approximately the same, and the T-wave in the ECG is larger than the R-wave.</p>	<p>Alternative derivation</p>

Derivation of a 1-channel ECG with adhesive electrodes

Preparation at the hardware standard (2-wire ECG cable, banana plug)	Glue the adhesive electrodes as shown in the figure and connect the electrode clips of the ECG cable to the electrodes
<p>Plug the adapters onto the two banana plugs.</p> 	

Derivation of a 3-channel ECG (only HRV scanner hardware plus)

Derivation of a 3-channel ECG with clamps	Derivation of a 3-channel ECG with adhesive electrodes
	

Technical Manual HRV-Scanner Hardware plus

The technical details on the HRV-Scanner Hardware plus can be found in the separate data sheet.

- 3 channel ECG
- Pulse wave over ear clip
- Breathing sensor over chest strap
- Pressure sensor for the Valsalva maneuver



Prepare the Breathing Sensor

Step 1)



Take:

- the respiratory sensor
- the breathing belt
- the fastening buttons

Step 2)



Insert the breathing belt from below through the side eyelet of the breathing sensor

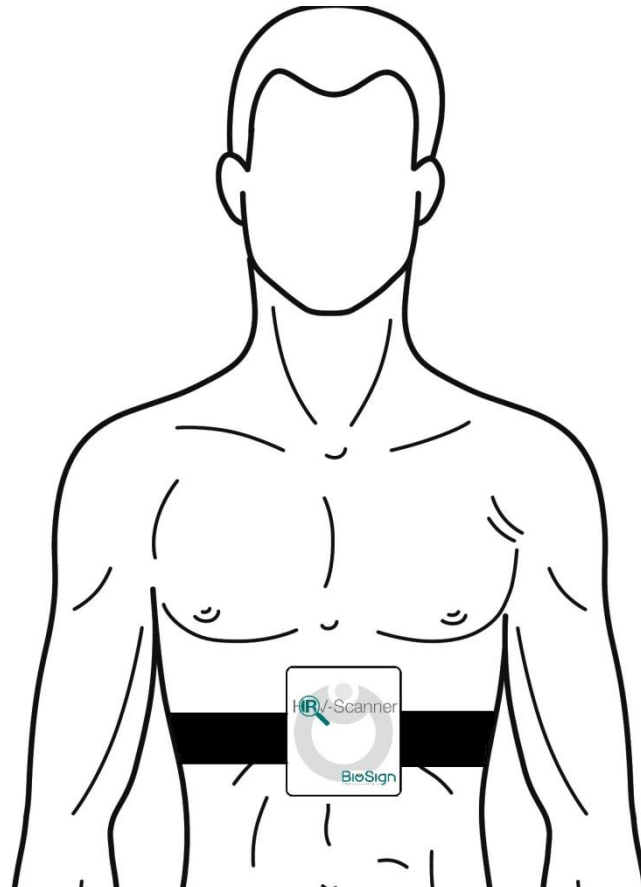
Step 3)

Close the end of the breathing belt with the help of the fastening button.

Step 4)

Do the same on the other side of the breathing sensor by running the other end of the breathing belt through the side eyelet and closing it as well.

The belt should be placed at the level of the lower ribs to detect chest and abdominal breathing. Place the sensor over the clothing (shirt).



The Valsalva pressure sensor set

The Valsalva pressure sensor set consists of 4 parts:

Mouthpiece		Filter	
Valve		Cap	

Before assembling the individual parts, please pierce a small hole of approx. 0.5 - 1 mm diameter e.g. with a pin into the red cap. This creates a flow and prevents the pressure from being built up by a closure of the glottis only with the mouth.



The pressure sensor set looks as follows:



Connect the Valsalva sensor to the HRV-Scanner plus hardware with a tube with a Luer lock at both ends. To do this, open the green cover on the filter and screw the tube on. The other end is connected to the metal connector on the HRV-Scanner plus hardware.

Spare parts for the Valsalva pressure sensor set can be obtained in our online shop or in the medical specialist trade.

Technical Manual

PC Hardware PC Requirements

- Operating system Windows 7/8/8.1/10
- USB slot \geq V 1.0
- minimum 300 MB free disk space
- 3D graphic card (\geq 32 MB)
- DirectX 9.0 or higher

Maintenance and Servicing

The HRV is not subject to a mandatory maintenance schedule. The user simply has to ensure that the device is only ever operated under the conditions stated in the Technical Data manual. In case of damage the device should be switched off immediately and sent for repair. Please note that opening the device will void any warranty claim.

Copyright

The software is protected by copyright and may only be used for private purposes. In particular leasing, swapping, transmitting, duplication, copying, distribution and editing in electronic systems in any form whatsoever are fundamentally prohibited.

Liability

The HRV is in no way intended to replace or act as a substitute for a medical diagnosis or therapy by a qualified medical professional. Neither BioSign nor their agents accept any liability for slightly negligent breaches of duty, as long as no essential contractual obligations, damages resulting in loss of life, physical injury or damage to health or warranties are involved or claims under the German Product Liability Act are affected.

In case of violations of essential contractual obligations BioSign shall only be liable for contract-typical, foreseeable damages. The statutory period of limitation for damage claims not due intentional behaviour for which BioSign is answerable is one year. This excludes damage claims from consumers resulting from faults in things supplied as new by BioSign as well as claims of compensation from suppliers in accordance with § 478 BGB (German Civil Code).

Warranty

The warranty period for HRV-Scanners is two years from the date of purchase (please retain your proof of purchase).

Technical details

Power Supply

Operating voltages	+5 V
Current consumptions	100 mA
Safety fuses	None

Pulse Wave

Sensor current for IR LED	c. 16 mA
Frequency range	c. 0.5 ...10 Hz
Sensor	M3405, connectible by plug
Scan rate	500 Hz

ECG

Type	an earth discharge L-R
Time constant	app. 3 s
Sensor	2 ECG clips, adhesive electrodes, connectible by plug
Scan rate	500 Hz

PC-Interface

Type	USB 1.1
Device class	HID (Human Interface Device)

Additional Data:

Safety	ECG part: power supply via insulated DC / DC converter. Signal isolation via optocouplers (Double insulation according to EN 60335-1, when connected to a PC) The device may only be connected to a PC provided with European certification mark!
Dimension (WHD)	app. 92 mm x 150 mm x 32 mm
Weight	app. 0.15 kg (without sensors)

Environmental Operating Conditions:

Temperature range	10 °C ... 40 °C
Rel. humidity	25% ... 95 %
Air pressure	700 ... 1200 hPa
No mechanical shocks or vibrations	

Environmental Conditions During Storage and Transportation

Temperature	-20 °C ... 60 °C
Rel. humidity	30 % ... 95% (non condensing)
Air pressure	700 ... 1200 hPa

The device must not be used on humans for the purpose of producing a medical diagnosis.

The HRV-Scanner is a protection class III device, compliant with EN 60335-1. The device conforms to the relevant EC ordinances. This is confirmed by the EC declaration of conformity.

Appendix - Literature

Literature SD2/SD1 ratio

- 1) Hoshi RA, Pastre CM, Vanderlei LC, Godoy MF. Poincaré plot indexes of heart rate variability: relationships with other nonlinear variables. Auton Neurosci. 2013 Oct;177(2):271-4. Epub 2013 Jun 5.
- 2) Stein PK, Domitrovich PP, Huikuri HV, Kleiger RE; CAST Investigators. Traditional and nonlinear heart rate variability are each independently associated with mortality after myocardial infarction. J Cardiovasc Electrophysiol. 2005;113-20
- 3) Makikallio TH, Hoiber S, Kober L, Torp-Pedersen C, Peng CK, Goldberger AL, Huikuri HV. Fractal analysis of heart rate dynamics as a predictor of mortality in patients with depressed left ventricular function after acute myocardial infarction. Am J Cardiol. 1999;83:836.
- 4) Laitio TT, Huikuri HV, Makikallio TH, Jalonen J, Kentala ES, Helenius H, Pullisaar O, Hartiala J, Scheinin H. The breakdown of fractal heart rate dynamics predicts prolonged postoperative myocardial ischemia. Anesth Analg. 2004; 98:1239-44.
- 5) Stein PK, Barzilay JI, Chaves PH, Mistretta SQ, Domitrovich PP, Gottdiener JS, Rich MW, Kleiger RE. Novel measures of heart rate variability predict cardiovascular mortality in older adults independent of traditional cardiovascular risk factors: the Cardiovascular Health Study (CHS). J Cardiovasc Electrophysiol. 2008 Nov;19(11):1169-74.
- 6) Stein PK, Domitrovich PP, Hui N, Rautaharju P, Gottdiener J. Sometimes higher heart rate variability is not better heart rate variability: results of graphical and non-linear analyses. J. Cardiovasc Electrophysiol . 2005 ; 16 : 954 – 959
- 7) Simula S, Vanninen E, Lehto S, Hedman A, Pajunen P, Syväne M, Hartikainen J. Heart rate variability associates with asymptomatic coronary atherosclerosis. Clin Auton Res. 2013 Nov 30.

