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Tele-Analyser clue medical with its diagnostic possibilities

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1. Telemedicine and ECG

„Telemedicine“ is generally an umbrella term for the use of multimedia communication and information technology in the health care sector. Strictly speaking telemedicine is the specific use of various technologies to apply individual medical technical services while bridging the physical distance between the doctor and patient. Telemedicine is a tend-setting innovation [Tebbe, U: Zukunft Telemedizin: innovative EKG- Übertragung und Evaluation. herzmedizin 20 (2003) No. 4, 184-188].

This reduces the relative risk all to often involved in delayed medical care and then resulting in a deterioration in the patient's prognosis. An essential requirement for this is that it is easy to use and is reliable, allowing an ECG to be recorded and, for example, telemetrically transmitted by the patient.

As is known, an electrocardiogram or ECG shows the bioelectric signals or potential differences that occur at the charge and discharge of stimuli in the heart over time. Direct signs of heart rhythm problems or indirect signs of acute or past heart attack can be interpreted from the ECG.

Figure 1 is a general outline of how a tele-ECG works: record, send, receive, evaluate.

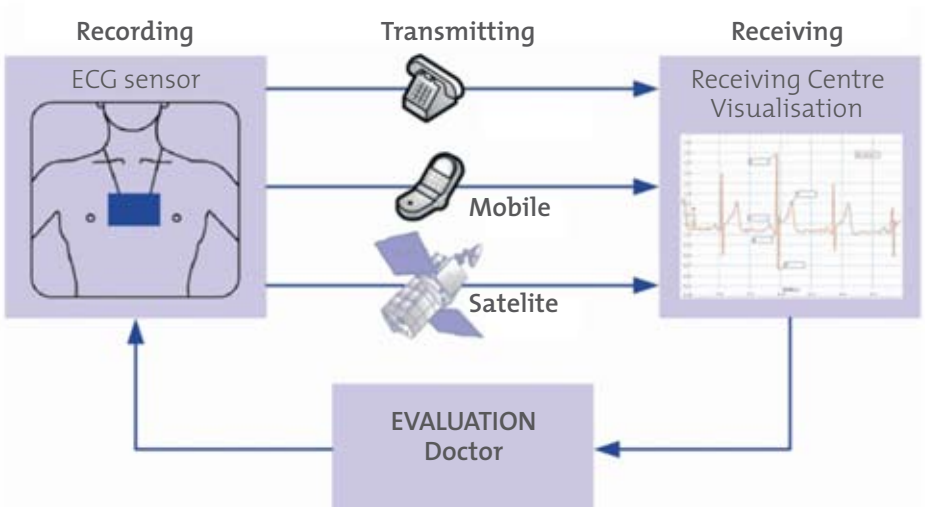

Fig. 1:
How a tele-ECG works. As well as providing an ECG, a telemetric extension can be added to include, for instance, blood pressure and blood oxygen saturation levels.

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2. The 1- or 3-channel tele-ECG and its information content

The principle prerequisites for a telemetric ECG application are simple handling, practicability and reliability of an electrocardiogram administered and telemetrically transmitted by the patient himself/herself. Taking these prerequisites into consideration, it is only possible to develop a 1- or 3-channel tele-ECG in which the quality of the information to be evaluated must be increased in comparison to previously prevailing telemetric quality. Further research focused on the analysis of the RR interval, which, as is generally known, is displayed the same way in all ECG derivations, so that additional derivations in this regard would not provide any additional information.
This quantitative RR analysis of the 1-channel ECG shall be called a „dynamic analysis", while the quantitative evaluation of the individual ECG sections of the 1-channel ECG („form analysis") shall be called a „static analysis".

2.1. Quantitative form analysis of the individual ECG sections of the 1- or 3- channel ECG: „static analysis"

The actual ECG interval, its form, is analyzed based on a derived ECG (Fig. 2) as the 1st step – analogous to the procedure of the physician. To do this, all known ECG intervals of the entire measuring time (2 minutes for clue medical) are superimposed, and the average interval, its form, is graphically displayed in such a way that a comparison with a normal course according to Fig. 3 is possible. A derived tele-ECG can only provide material for the analysis of time values, but no amplitudes. Therefore, the physician can compare target values with actual values very simply and immediately.

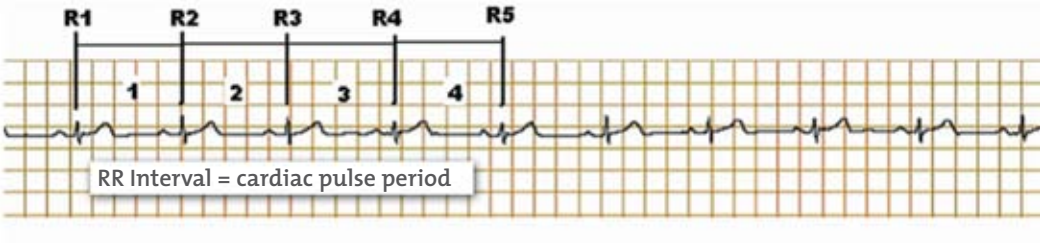

Fig. 2:
time section from a 1-channel tele-ECG including marked RR-interv... as associated cardiac cycles

Special evaluation of time values for the calculated ECG interval

As is generally known, we differentiate between the atrial and ventricular segments in the ECG course. The atrial segment begins with the P wave. It is the expression of the spread of the stimulus over both atria. During the subsequent PQ segment, the atria are stimulated as one. Repolarization in the atria coincides with the initial deflection of the ventricular segment. The ventricular segment runs from the beginning of Q to the end of T. The QRS group is the expression of the spread of stimulus over both ventricles, while the T wave is the expression of the ventricular repolarization. In between these is the ST segment, which – analogous to the PQ segment in the atrial segment – indicates the total excitation of the ventricular myocardium. Occasionally, a so-called U wave is also visible following the T wave. This is considered the expression of the repolarization of the cardiac conduction system.

The ***PQ interval***, the so-called conduction time, includes the period from the beginning of the atrial excitation to the beginning of the ventricular excitation. It is normally ***shorter than 0.2 seconds.*** Prolongations of more than 0.2 seconds indicate disturbances in conduction, usually in the area of the AV node or the bundle of His. A prolongation of the ***QRS group of more than 0.12 seconds*** indicates disturbances in the intraventricular spread of stimulus. The ***QT interval is dependent on frequency***, like the myocardial action potential. As the heart rate increases (= shortening of the RR interval), the QT interval is reduced.

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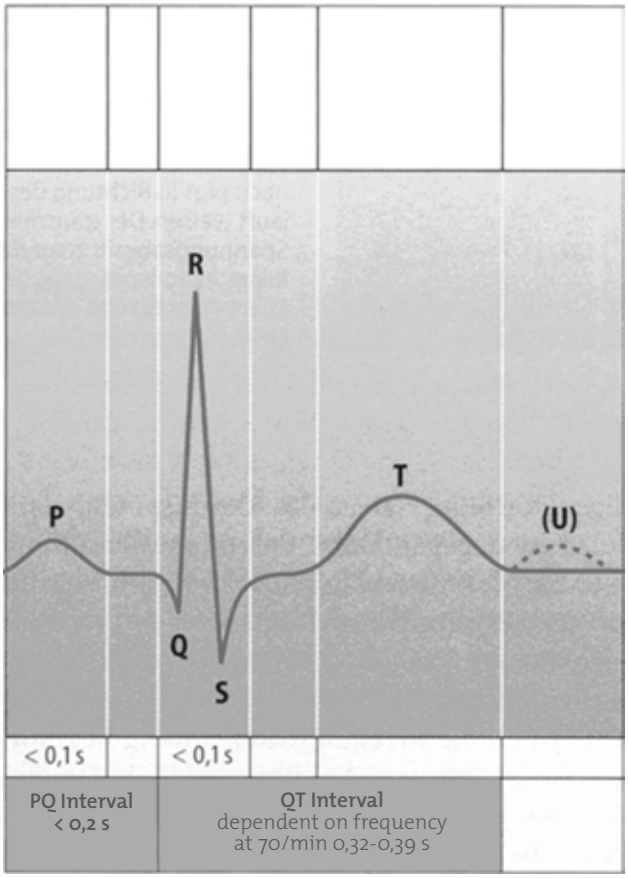

Fig. 3:
Normal ECG including normal time values [from Schmidt, R F and G Thews: Physiologie des Menschen. 27th edition., Springer Berlin Heidelberg New York]

It is also known that the ***QT time (see figure 3) can be used to stratify the cardiovascular risk.*** (Die QT-Zeit, die instabile Angina pectoris und das kardiovaskuläre Risiko. In: The European Cardiologist dated 29.3.04). A prolonged QT-interval occurs as a result of a series of clinical conditions, such as acute myocardial ischemia, myocardial infarctions, cardiomyopathy, cardiac insufficiency, stroke or metabolic disorders.

2.2 Analysis of the R-R intervals, associated FFT and cardiovascular parameters that can be derived from this. Spectral measured values as quantitative results for the cardiovascular condition: „dynamic analysis“

If for each heart activity μ within a defined tracing time the associated cardiac pulse period T_H (μ) is taken (i.e. the R-R-intervals according to figure 2) and if these are applied as a function of the corresponding heart activity, this shows a characteristic cardiovascular function of what is known as the „***Tachogram of cardiac pulse periods***“. This is a system constant for the ECG tracing time, that is the same in all other ECG tracings. For this reason only one ECG tracing is required for a „dynamic analysis“ of this kind

As there is an established reciprocal connection between a signal cycle period T and the resulting signal frequency, i.e. T = 1/ f, the equivalent „***tachogram of heart rates***“ can be shown.

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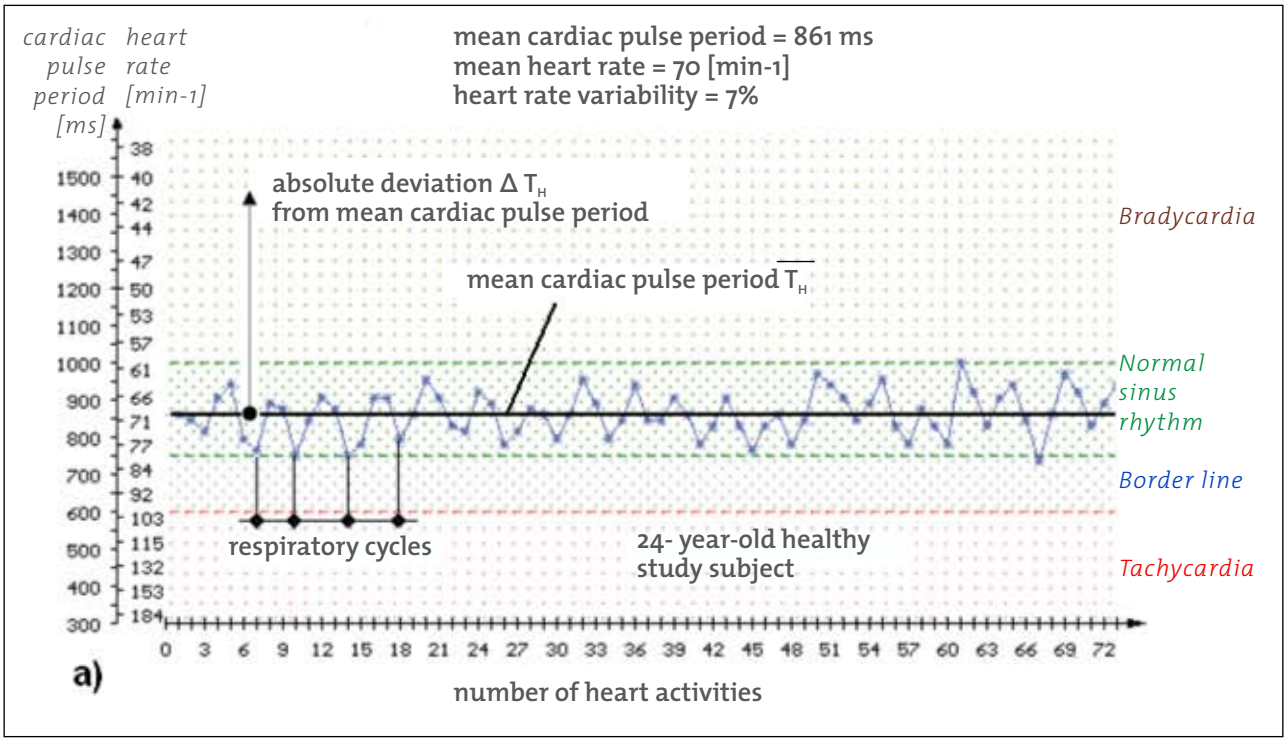

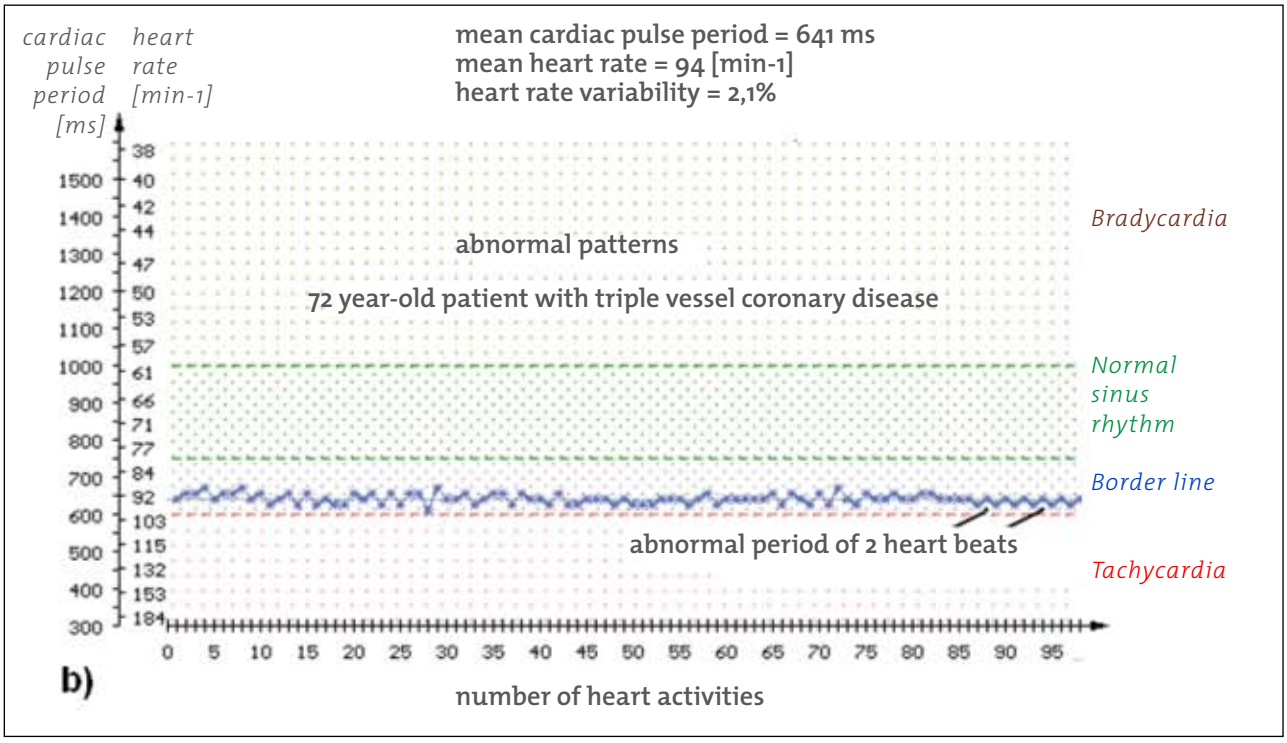

fig. 4:
1 minute segment of a tachogram of cardiac pulse periods (R-R intervals) or their reciprocal value heart rate including definition of cardiac pulse period deviation Δ T_H:

a) 24 year old healthy study subject: there is a clear respiratory sinus arrhythmia with the respiratory cycles.

There is also a clear heart rate variability.

b) 72 year old patient with triple vessel coronary disease: as well as a high mean heart rate of 94 min-1 the heart rate variability is evidently low.
There is no respiratory sinus arrhythmia,
at the end of the 60 second tachogram the heart cycles change periodically with the abnormal period with 2 heart beats.

Figure 4 shows the a 1 minute extract of a tachogram of the cardiac pulse periods (R-R intervals) in a 24 year old healthy study subject **(figure 4a).** There are almost periodic respiratory dominant oscillations of the cardiac pulse periods („respiratory sinus arrhythmia"), the deviations of the cardiac pulse period from the mean or the resulting heart rate variability is clearly evident, the heart rate fH = 70 min-1 is normal.
Figure 4 b on the other hand, shows a 72 year old patient with triple vessel coronary disease with abnormal patterns: as well as the high mean heart rate of 94 min-1 the heart rate variability is also obviously low. There is no respiratory sinus arrhythmia.

According to Wehr [Wehr M: Praktische Elektrokardiographie und Elektrophysiologie des Herzens. Ein diagnostischer und therapeutischer Leitfaden für Studenten und Ärzte. 1st edition; Fischer Stuttgart, New York1988] the heart rate should be **cardiologically divided** into the following:

- **Normal sinus rhythm: 60 ... 80 min-1** [cardiac period time = 750 ... 1000 ms]
- **Bradycardia: ffi 60 min-1** [cardiac period time ffl 1000 ms]
- **Tachycardia: ffl 100 min-1** [cardiac period time ffi 600 m**s]**
- **Borderline: 80 ... 100 min-1** [cardiac period time = 600 ... 750 ms]

To be able to make an assignment of this kind, the arithmetic **mean of the cardiac pulse** periods TH in [s] is established from the tachogram and thus for a determined measuring time from the established N R-R intervals

$$T_H = \frac{1}{N}\sum_{\mu=1}^{N} T_\mu \qquad (1)$$

The mean heart rate f_H can then be calculated, with the following conversion:

heart rate f_H (Hz) = 1 / heart period time TH [s] (2a)

or

heart rate f_H [min-1] = 60 / cardiac pulse period TH [s]. (2b)

The changes in the cardiac pulse period that occur with each heart beat under physiological conditions are an expression of the activity of the **automonic nervous system** and its „counterparts", the **sympathetic and parasympathetic nervous system**. This paper therefore aims to derive the applicable information or quantitative measured values from a cardiac pulse period tachogram. The aim, in particular, is to address and resolve the issue of a possible „**stress**" curve, although there is as yet no generally applicable scientific definition of stress. The fact that there is a link between physical stress reactions and the autonomic nervous system is now, however, undisputed.

„Stress" has long been established as a medical and psychological problem. It is a phenomenon that affects all age groups and all social classes. Many people try to compensate their day-to-day stress, by, for example, smoking: the greater the stress, the more cigarettes they smoke. This in no way actually deals with the stress - it simply „numbs" it. It is known that a very simple and effect way to combat stress is sport. Stress that has built up in the body is discharged during physical exertion and is then processed without having a harmful impact on our health. Regular and sensible sport keeps the body fit, give a new sense of self-confidence and boosting the body's natural defences against stress. The cardiovascular system is stronger.

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It is estimated that more than half of all illness can be attributed to stress.
These are usually psychosomatic diseases and the so-called civilisation diseases.

Doctor and expert in stress research H. Selye, often described as the „father of stress research", coined the word „stress" in about 1950 to express the conditions „strain" or „exertion".

From signal theory [Woschni, E G and M Krauß: Informationstechnik. Arbeitsbuch Signal-System-Information. Dr. A Hüthig Heidelberg 1976], it is known that any random time function x (t) can be broken down to the (arithmetic) mean x (t) and the deviation Δ x (t), so that the following applies:

$$x(t) = \overline{x(t)} + \Delta x(t). \tag{3}$$

Basically, it is this kind of signal x(t) that is present in the „cardiac pulse period R-R interval tachogram". As there is only a tracing for the time after each cardiac activity μ, instead of x(t) the following should be based on the previously introduced terminus TH (μ).

Analogue to the above general signal breakdown, the equation below (see figure 4a) applies specifically to the R-R interval:

$$T_H(\mu) = \overline{T_H} + \Delta T_H(\mu), \tag{4a}$$

where T_H (μ) represents the time of the μ cardiac activity, where TH represents the arithmetic mean for the underlying measuring time and where ΔTH (μ) represents the absolute deviation of the cardiac pulse period of TH at this time point μ.

And so the following equation applies to the absolute deviation of the cardiac pulse period at the time of the μ cardiac activity from the established arithmetic mean:

$$\Delta T_H(\mu) = T_H(\mu) - \overline{T_H} \ . \tag{4b}$$

The arithmetic mean TH generally depends on age a (defined in „years").
For comparison, this is to be based on what is known as the Jose Equation [Jose, A D: Effect of combined sympathetic and parasympathetic blockade on heart rate and cardiac function in man. Am. J. Cardiol. 18 (1966), 476-478], if the reciprocal heart rate is used instead of the cardiac pulse period:

$$f_H\,[\mathrm{min}^{-1}] < 118.1 - 0.57\,a. \tag{5}$$

Figure 5 is the graphic representation of this. It follows that the resting heart rate in a recumbent position will fall as the patient gets older.

As well as the (mean) heart rate depending on age, it is also known from physiology that activity of the automonic nervous system also has an important role to play. While the sympathetic stimulation reduces the beating time, i.e. increases the heart rate by releasing adrenalin and noradrenalin, the parasympathetic nervous system largely reduces the heart rate by releasing acetylcholine. The latter particularly applies if the patient is resting in a recumbent position (vagus nerve stimulation)

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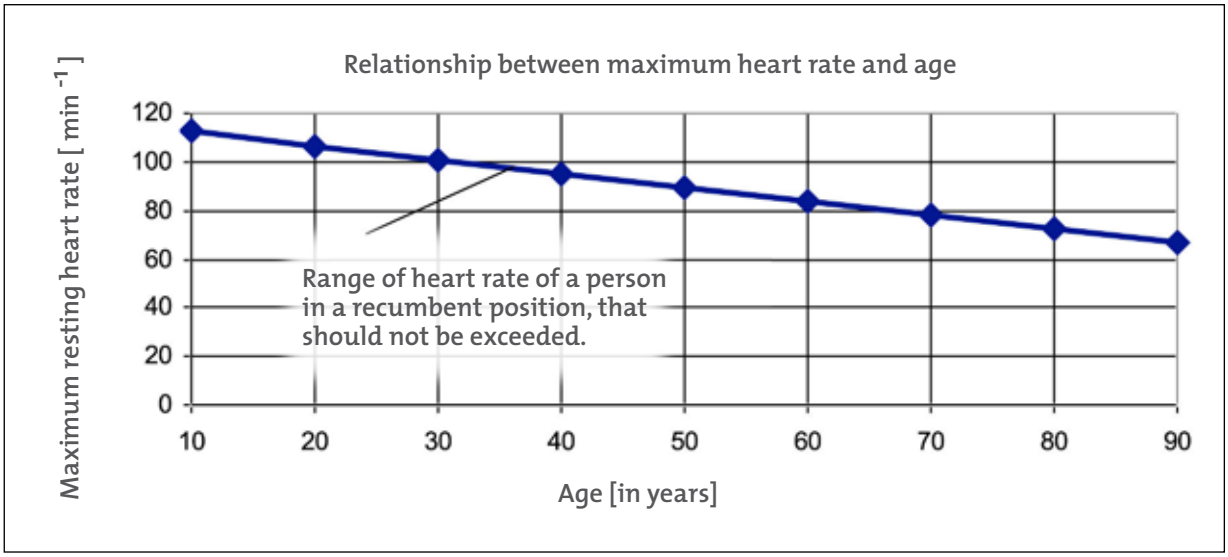

Fig. 5:
Relationship between the resting heart rate of a recumbent patient and age according to Jose

The above mentioned impact of the automonic nervous system on the assessment of the cardiovascular condition by the arising (mean) heart rate is presented in the literature with too great a focus on the „heart rate variability" that still has to be deduced, as will later be shown. This is considered to be a serious flaw, in particular when assessing „stress" or „strain", or its „counterpart" - recovery.
This paper will therefore aim to find an extended integral quantitative measure.

To derive special time indices for the heart rate variability

The absolute deviation of the cardiac pulse period introduced in the Gl. (4b) at the time of the μ heart activity from the established arithmetic mean can be used to apply well-established mathematical calculations to calculate the mean square cardiac pulse period deviation, known in mathematical statistics, signal processing and signal theory as the „**standard deviation**" STH [Woschni, E G und M Krauß: Informationstechnik. Arbeitsbuch Signal-System-Information. Dr. A Hüthig Heidelberg1976; Schrüfer, E: Signalverarbeitung. Numerische Verarbeitung digitaler Signale. Hanser München Wien 1990; Krauß, M und E-G Woschni: Meßinformationssysteme. Kennfunktionen, Gütekriterien, Optimierung. 2nd edition VEB Verlag Technik 1975] and that corresponds to the „**absolute heart rate variability**" with the dimension „seconds".

$$s_{TH}[s] = \sqrt{\frac{1}{M-1}\sum_{\mu=1}^{M}[T_H(\mu) - \overline{T_H}]^2}$$

In this equation **M** is **the number of („normal") RR intervals of the measuring time** that can be assessed. This means that a screen test must first be carried out. This assumes the general specification, **that premature extra beats (25% prematurity related to the mean R-R interval) and the post-extrasystolic beat from the derived time parameters of the cardiac pulse period tachogramme should be eliminated** . The use of the mean cardiac cycle for the underlying measuring time appears to be mathematically sound and generally practical for these algorithms in the cardiac pulse period analyses. **Extra beats are not taken into account when calculating the mean cardiac cycle either.**
In the R-R tachogram, however, all cardiac activity underlying clue medical that is derived from the mathematical identifying algorithms including extra beats is shown. This means that, for instance, the presence of general heart-rhythm abnormalities is shown visually.

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To minimise the impact of the established day and night rhythm, relative values are introduced. This means that the absolute variability of the cardiac pulse period STH with the dimension „seconds“, the standard deviation, is related to the mean cardiac pulse period with the same dimension and is then multiplied by factor 100 so that the value can be expressed as a percentage.
This cardiovascular specific value represents a „variations coefficient“ and is abbreviated to „**(relative) heart rate variability**“ VHF ΔHF) or HRV [Baumert, J-H, A W Frey and M Adt: Analyse der Herzfrequenzvariabilität. Grundlagen, Methodik und mögliche Anwendung in der Anästhesie. Anaestesist 44 (1995), 677-686; Esperer, H-D: Die Herzfrequenzvariabilität, ein neuer Parameter für die nichtinvasive Risikostratifizierung nach Myokardinfarkt und arrhythmogener Synkope. Herzschr. Elektrophys. 3, 1-16 (1992); Walter, Th, G Grießl and A Neugebauer: Die Messung der Kurzzeit-Herzfrequenzvariabilität in Ruhe und unter Belastung – Vorstellung einer neuen Methode. Herz/Kreisl. 27(11/95), 366-369]:

$$HRV = VHF = \Delta HF\,[\%] = \frac{s_{TH}\,[s]}{T_H\,[s]}\,100\,[\%]$$

This variation coefficient, the (relative) heart rate variability, is therefore a **mean value** and - as with the mean cardiac cycle introduced earlier - depends on age.
With increasing age the heart rate variability falls - just before death it disappears altogether. The HRV can also virtually reach zero in diabetics with final stage **cardiovascular automonic neuroptathy**; the heart rate is completely stationary with tachycardia [Ziegler, D et al. Klinik, Diagnostik und Therapie der kardiovaskulären autonomen Neuropathie. Dt. Ärztebl 1996; 93: A-1262-1268 (book 19); Reichel, G.: Apparative Diagnostik peripherer vegetativer Funktionsstörungen. psycho 19 (1993) No. 5, 319-325].

The **relation of the absolute and relative heart rate variability and age** is shown in **figure 6**. It is evident that both heart rate variabilities reduce as the patient gets older.

In this case with the objective of „telemetric application“, for the sake of algorithmic simplicity , the absolute and relative standard deviations STH or HRV = VHF are used, even if in practice the number of defined heart rate variability indices is actually much higher [see for example Esperer, H. D. (1995): Physiologische Grundlagen und pathologische Aspekte der Herzfrequenzvariabilität beim Menschen. Herzschr. Elektrophys. 5, 1-10].

The FFT analysis of the absolute deviation of the cardiac pulse period from the arithmetic mean

If the absolute deviation of the cardiac pulse period introduced earlier at the time of the μ heart activity from the established arithmetic mean T_H

$$\Delta T_H(\mu) = T_H(\mu) - \overline{T_H}$$

is applied using a **fast Fourier transformation** (FFT) rather than a time average, this results in what is known as the (power) spectrum of the heart rate variability [or more precisely: „**the (power) spectrum of the absolute deviation of the cardiac pulse period from the mean** T_H“].

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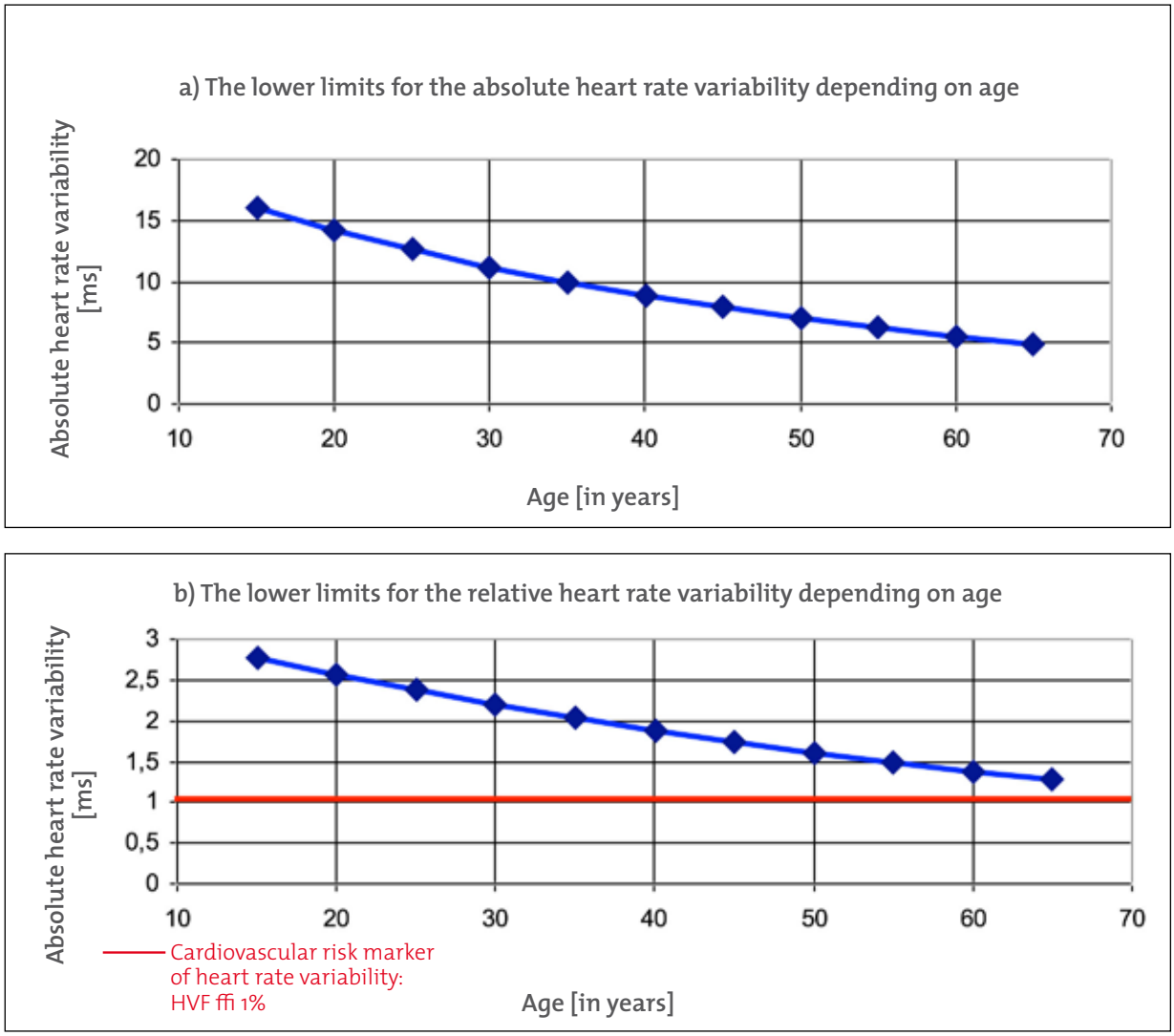

Fig. 6:
The lower limits for the absolute [a)] and [b)] relative heart rate variability depending on age as 2.5% percentiles [from Agelink MW et al: D (2001) Standardized tests of heart rate variability: normal ranges obtained from 309 healthy humans, and effects of age, gender, and heart rate. Clinical Autonomic Research 11: 99-108 (2001)]. The values should be evaluated so that only in 2.5% of the tested study subjects were the values were lower than the value defined for that age. This can therefore also be used as the lower limit for normal or abnormal HRV findings. The b) graph can be used as a general and asymptomatic cardiovascular risk marker for the relative heart rate variability: HVF ffi 1 %.

Generally speaking the above graphs show that the heart rate variability falls with increasing age. Agelink provides the following **examples** of this:
Example 1: a resting SDNN of 32.5 ms is measured in a 42 year old study subject („normal" > 8.9 ms). Interpretation: normal.
Example 2: a resting SDNN of 7.5 ms in measured in another 42 year old study subject („normal" > 8.9 ms) Interpretation: abnormal.
Example 3: a resting SDNN of 7.5 ms is measured in a 65 year old study subject („normal" > 8.9 ms) („normal" > 4.9 ms). Interpretation: normal.
Agelink does, however, point out that there is a wide range of individual conditions (smoking, stress, infections, etc) that can influence the results. If there results are not within the normal range, it is therefore important to ask a doctor. Of course, if the results are normal this is no guarantee that the person is healthy, and this should not taken the place of a doctor's appointment if there are existing health problems.

[***Note on the often-cited FFR spectrum of the „heart rate variability"***:
"Variability" is a fixed term in mathematical statistics, signal processing and the sciences. Generally the following applies: Variability = dispersion. This does not describe the curve of a time function, but only the measures of central tendency of a statistical distribution derived from the time function including measures of variability.
The latter gives an idea of how strong the individual values are dispersed around the measures of central tendency. A frequency spectrum of a quantity that is time-independent is a concept that hardly seems appropriate or even possible, although it is often discussed in the medical literature - it is more practical to use an FFT analysis, the absolute deviations of the cardiac pulse period from the cardiac cycle mean or the oscillations of the R-R intervals.]

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[***Literature on the FFT analysis. See appendix 2,*** specifically: Horn, A: Diagnostik der Herzfrequenzvariabilität in der Sportmedizin - Rahmenbedingungen und methodische Grundlagen. Diss, Fakultät für Sportwissenschaft, Ruhr-Universität Bochum 2003; Bürklein, M, Vogt L and W Banzer: Meßverfahren zur Erfassung der Herzfrequenzvariabilität – Eine vergleichende Studie. Cross validation of heart rate variability measurements before and after exercise. Deutsche Zeitschrift für Sportmedizin. Volume 56, No. 12 (2005); Löllgen, H. (1999): Neue Methoden in der kardialen Funktionsdiagnostik: Herzfrequenzvariabilität. Deutsch. Ärztebl. 96, A2029-A2032; Moser, M et al: Das autonome Bild als Methode zur Darstellung der Rhythmen des menschlichen Herzschlags. Vortrag auf „Diagnostik- Workshop" 25. - 26 November 2003 Bad Bleiberg/ Österreich; Esperer, H-D: Die Herzfrequenzvariabilität, ein neuer Parameter für die nichtinvasive Risikostratifizierung nach Myokardinfarkt und arrhythmogener Synkope. Herzschr. Elektrophys. 3, 1-16 (1992)],

Figure 7 shows an FFT spectrum derived from a cardiac pulse period tachogram of a 20 year old person with a healthy cardiovascular system, where the tracing time was 3 minutes. For physical-mathematical reasons the range of up to 0.5 Hz should be used as a basis for this. As a frequency analysis of this kind is only carried out for the component ΔTH (μ) [the absolute deviation of the cardiac pulse period from the mean TH] and as this has no constant component, the value at f = 0 Hz is also zero. The overall signal TH (μ) does, however, have the constant component already discussed, namely the arithmetic mean TH. .

There is currently no actual standard for the „heart rate variability analysis" FFT spectrum, but there is a whole host of results and papers as can be seen in appendix 2. For the spectrum analysis, reference is more and more often made to the **Guidelines laid down by the Task Force of European Society of Cardiology dated 1996 and the „North American Society of Pacing and Electrophysiology" [Heart rate variability. Standards of measurement, physiological interpretation and clinical use. European Heart Journal (1996) 17, 354-381].** The groundbreaking paper by Bürklein, M, Vogt L and W Banzer: Meßverfahren zur Erfassung der Herzfrequenzvariabilität – Eine vergleichende Studie. Cross validation of heart rate variability measurements before and after exercise. Deutsche Zeitschrift für Sportmedizin. Volume 56, No. 12 (2005) also relies on the above publications.

This task guideline and the Bürklein paper are the basis of the following FFT analysis, as can be seen in figure 7. This characterises and identifies the typical frequency ranges for the case of a so-called „short term analysis" of approximately 2 to 5 minutes ECG recording time in accordance with the task guideline. This shows the influence of the **vegetative components of the cardiovascular system,** but also the influence of the 0.4 - 0.5 Hz range, that has rarely been the subject of any investigation.

- **Frequency range „Low Frequency" 0.04 to 0.15 Hz**: This range can be pri marily allocated to the sympathetic nervous system cardiovascular activity, thus also to mental and physical stress. The literature states that there can also be a parasympathetic component here.
  Physiology teaches us that the Traube-Hering oscillations in this range are also an expression of blood pressure cycles? In the literature, this low frequency range is assigned to general „tensions" or „stress".

- **Frequency range „High Frequency" 0.15 to 0.4 Hz:** the parasympathetic (vagus) activity that occurs is typical for this, and thus also the heart rate fluctuations of the respiratory sinus arrhythmia synchronous with respiration [Horn, A: Diagnostik der Herzfrequenzvariabilität in der Sportmedizin - Rahmenbedingungen und methodische Grundlagen. Diss, Fakultät für Sport wissenschaft, Ruhr-Universität Bochum 2003].

- The spectrum surface ratio between the LF and HF components is described by some authors as the **sympathovagal balance.** It is, however, important to bear in mind that a change in the LF components - as mentioned above - can be caused by either the sympathetic or the parasympathetic nervous system. This tracing poses a problem that has not yet been solved, and a solution will be sought in the following sections.

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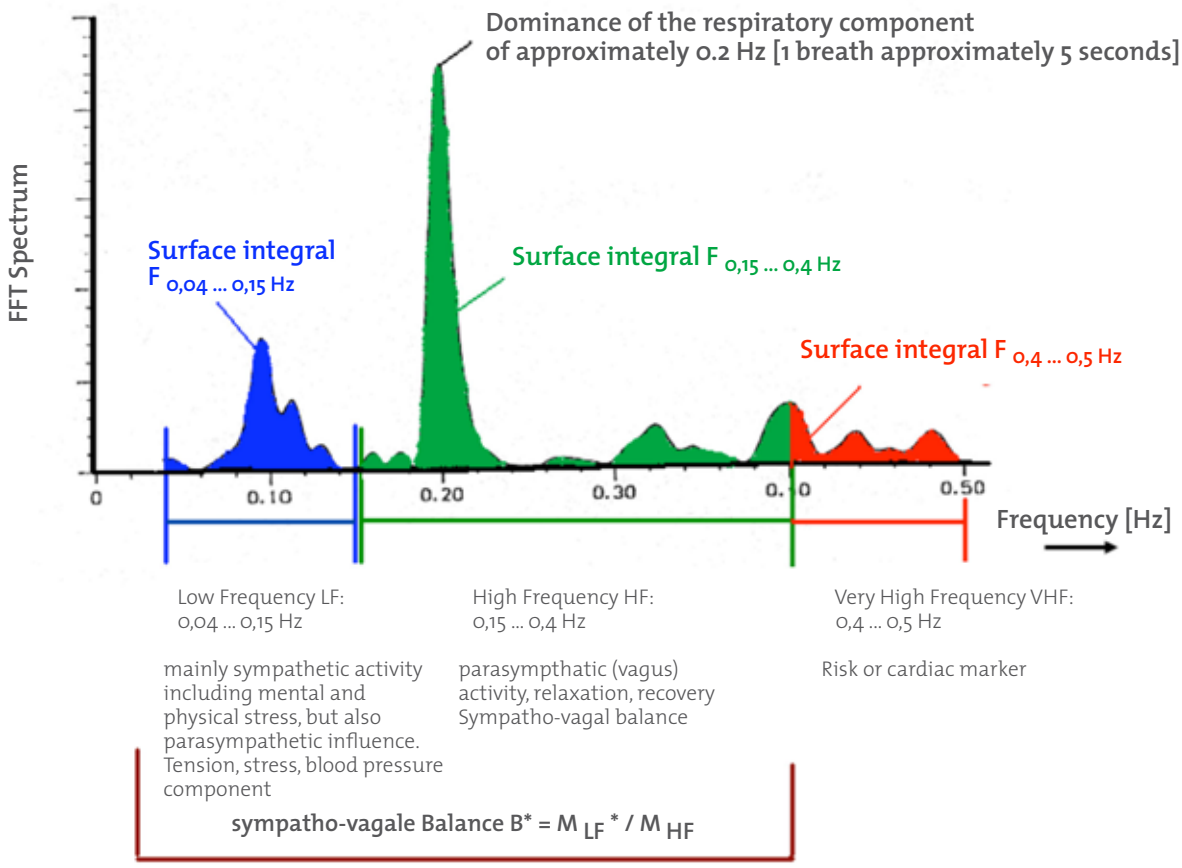

Fig. 7:
An FFT spectrum from the tachogram of the cardiac pulse periods in a 20 year old healthy study subject and a 3 minute tracing time [from Baumert, J-H, A W Frey and M Adt: Analyse der Herzfrequenz-variabilität. Grundlagen, Methodik und mögliche Anwendung in der Anästhesie. Anaestesist 44 (1995), 677-686] including frequency range characteristics for LF, HF and VHF

• ***Frequency range „Very High Frequency" 0.4 to 0.5 Hz:*** Back in 1986 Meyers et al. [Meyers GA, Martin GJ, Magid NM et al: Power spectral analysis of heart rate variability in sudden cardiac death: Comparison to other methods. IEEE Trans Biomed Engin 33:1149 (1986)] recognised that in high risk cardiac patients this frequency range, not assigned to the vegetative component of the cardiovascular system, was the **„most effective parameter to assess the risk for sudden cardiac death with 100 % sensitivity and specificity** Espere, H.D.: Die Herzfrequenzvariabilität, ein neuer Parameter für die nichtinvasive Risikostratifizierung nach Myokardinfarkt und arrhythmogener Synkope. Herzschr. Elektrophys. 3, 1-16 (1992)]. Meyers et al. investigated parameters on the heart rate variability as well as the FFT spectra in 6 patients with heart disease who suffered sudden cardiac death, 6 patients with heart disease with complex ventricular arrhythmia and 6 patients with a healthy cardiovascular system. Their findings resulted in the above observation.

The low frequency components of approximately 0.01 to 0.05 Hz not marked in figure 7 show, for instance, the thermoregulartory influence. The literature does not yet represent this at all clearly. As a frequency analysis and assessment of this kind, in terms of the know sampling theorem of signal theory [Krauß, M und E-G Woschni: Meßinforma-tionssysteme. Kennfunktionen, Gütekriterien, Optimierung. 2nd edition VEB Verlag Technik 1975] would require much longer ECG tracing times than the telemedical appli-cation in this case allows, this frequency range will not be included here. An FFT spect-rum analysis will therefore only be carried out for the characteristic **frequency range of 0.04 to 0.4 Hz**, the more so as clue medical records activity of the vegetative components of the cardiovascular system.

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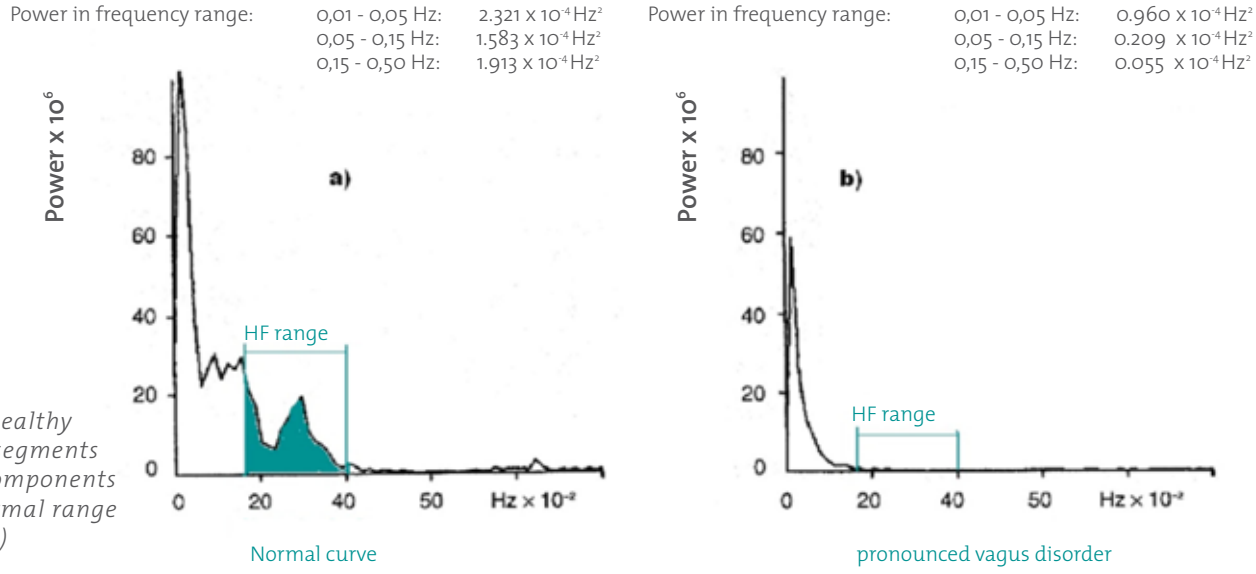
As is explained by, among others, Horn [Horn, A: Diagnostik der Herzfrequenzvariabilität in der Sportmedizin - Rahmenbedingungen und methodische Grundlagen. Diss, Fakultät für Sportwissenschaft, Ruhr-Universität Bochum 2003], the methodical requirements to carry out an FFT analysis are, for instance, **stationarity and the absence of disturbance in the R-R tracing**. These should be ensured in a test R-R series (**trend elimination**, filtering artefacts, resampling, etc). As stationarity is required, according to Horn a frequency analysis of this kind is only suitable for short tracing times of 2 to 5 minutes „Short term analysis". This corresponds exactly to the planned practical application at clue medical. A prerequisite for a quantitative tracing and its comparison is that the ECG is carried out with the patient in a recumbent position, and that the tracing is not started until the cardiovascular system is in a stationary condition. This takes about 2 minutes. Generally the literature does not provide any consistent information on the necessary tracing time. Schubert [Schubert, E: Welche Erkenntnisse können aus Untersuchungen des Herzrhythmus gewonnen werden? Dtsch. Gesundheitswesen 39, 845-855 (1984)] continues to maintain that a tracing of about 100 normal heart beats in an ECG allows a representative calculation of cardiovascular parameters in the time range. This number is barely sufficient for a frequency analysis in the range of 0.04 ... 0.15 Hz, but a total tracing time of 2 minutes under the condition that the „cardiovascular system is in a stationary condition" prior to tracing appears to be sufficient.

In accordance with Reichel [Reichel, G: Apparative Diagnostik peripherer vegetativer Funktionsstörungen. psycho 19 (1993) No. 5, 319-325] **figures 8 and 9** aim to show the typical FFT **power** density spectra of the absolute deviation of the cardiac pulse period from the mean TH, where the power spectrum corresponds to the squared FFT amplitude spectrum..

Figure 8 shows the contrasting spectral power density curves in a 35 year old healthy individual and in another 35 year old patient with type I diabetes and moderate somatovisceral polyneuropathy, where the ECG tracing time is 5 minutes for each. The longer tracing time allows the low frequency range of 0.01 - 0.04 to be approximated. While the components in the range differ only very little, the differences in the other ranges are very clear. In the purely vagus-associated HF band, the spectrum power is extremely reduced, so that the diagnosis of severe vagus disorder with sympathetic cardiac innervation had to be made.

Fig. 8:
Power spectrum density of the heart rate variation with patients resting, in a recumbent position and an ECG reading time of 5 minutes in accordance with Reichel



a) 35 year old healthy subject: In all 3 segments the frequency components are within a normal range (not shown here)

b) 35 year old subject with type I diabetes with medium grade somatovisceral polyneuropathy
The differences in the MF and HF ranges are significant, especially in the HF range.

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Power in frequency range: 0,01 - 0,05 Hz: 0.081 x 10^{-4} Hz^2
0,05 - 015 Hz: 0.043 x 10^{-4} Hz^2
0,15 - 0,50 Hz: 0.038 x 10^{-4} Hz^2

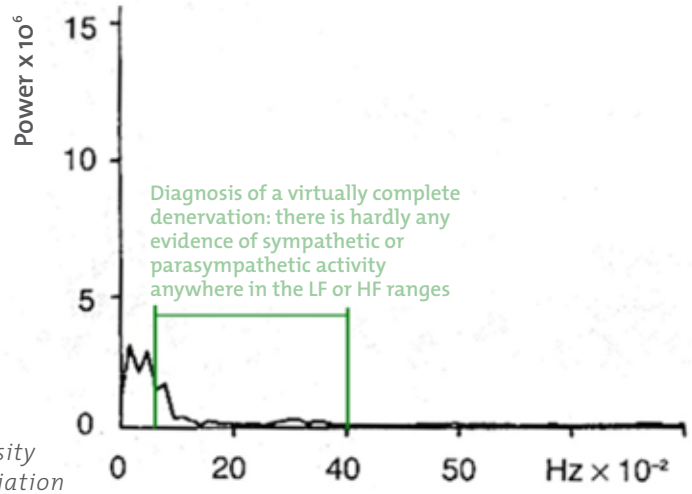

Fig. 9:
Power spectrum density of the heart rate variation in a 37 year old patient with Guillain-Barré-Strohl syndrome in accordance with Reichel, in resting and in a recumbent position. There is a significant loss in performance in both frequency ranges (note: other measuring criteria than used in figure 7)

Figure 9 shows the spectrum in a 37 year old patient with full developed Guillain-Barré-Strohl syndrome.
The segments in all frequency areas are significantly reduced, while the ordinate measuring criterion is much more sensitive than in figure 8 so that the components can still be shown.

A diagnosis of virtually complete cardiac denervation was made.

3. The derivation of spectrum measured values including the sympathovagal balance of the derived (power) spectrum of heart rate variability derived in section 2.

As can be seen in the course of the spectrum power densities in figures 7 to 9, the amplitude segments in the defined frequency ranges can be qualitatively compared. There are obviously typical abnormal patterns as well as typical normal patterns.

By determining the integral area dimensions for the frequency ranges 0.04 ... 0.15 Hz and 0.15 .... 0.4 Hz, and dividing these by the normal values,
the **„spectrum measured values" M** can be introduced, as can be seen below:

Determining the normal values:

- The cardiovascular values are taken from study subjects with a healthy cardiovascular system aged between 18 to approximately 30 with the following restrictions:
  Non-smokers, no physical exertion in the last 60 minutes before the readings were taken.
- The readings were taken with the patients in a recumbent position.
- Approximately 2 minutes resting before starting the readings
- Adhesive electrodes used for the resting ECG.

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Associated surface integrals (sums) F are determined from the derived FFT spectrum for the above test persons for **one** tracing of 120 seconds, to which the **spectrum power normal amplitudes A (nfA** occurring at the discrete frequencies nfA [fA = sampling frequency] are added.

• *LF-range 0.04...0.15 Hz:*
$F_{normal\ 0.04\ -\ 0.15\ HZ} = \sum A\ (nf_A)$

• *LF-range 0.15...0.4 Hz:*
$F_{normal\ 0.15\ -\ 0.4\ HZ} = \sum A\ (nf_A)$

The mean normal range for these frequency ranges is determined from these „normal surface totals": Mean value ± standard deviation.

If any random spectrum is then derived, the surface sum F_A for the underlying frequency ranges LF, HF is formed and is related to the associated normal surface value.
These relative values are termed „**spectrum measured values M**".

$$M_{LF} = \frac{F_{0,04\ ...\ 0,15\ Hz}}{\textit{mean surfaces - normal value}}\ 100\,[\%]$$

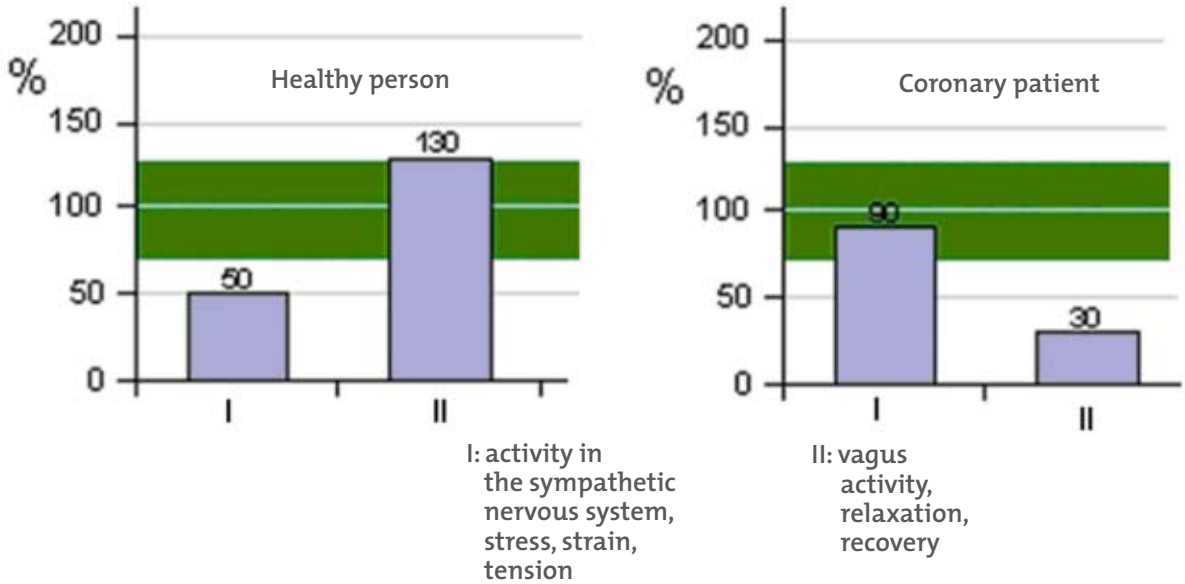
$$M_{HF} = \frac{F_{0,15\ ...\ 0,4\ Hz}}{\textit{mean surfaces - normal value}}\ 100\,[\%]$$

As this spectrum measured value is always related to the normal values of the corresponding frequency range, it is immediately apparent if there are automonic disbalances. **Figure 10** shows 2 typical cases for spectrum measured values, derived from the cardiac pulse period tachograms (R-R intervals) of a tele-ECG with the following results:

• Healthy study subject: hardly any stress, good resting condition with pronounced respiratory sinus arrhythmia (as in figure 4a)),

• Coronary patient with low recovery component (corresponding to figure 4b).

Fig. 10: Characteristic examples of spectrum measuring values M: left: for a normal study subject corresponding to figure 4a), right: for a coronary patient as in figure 4b).



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Specifying the derived spectrum measured values

Because, as mentioned previously, the low frequency range of 0.04 to 0.15 Hz can be assigned to both sympathetic nervous system or possibly also parasympathetic cardiovascular activity, while the high frequency range of 0.15 to 0.4 Hz is assigned solely to parasympathetic (vagus) activity, it should be queried whether the derived spectrum measured value MLF for the LF range can be specified so that it only characterises sympathetic nervous system activity. This would make it possible for the first time to define a real „sypatho-vagal balance" between the sympathetic and vagal components. Malliani's group, based in Milan, tackled a similar issue [Malliani, A et al: Cardiovascular neural regulation explored in the frequency domain. Circulation 84: 482-492, 1991].

On the basis of signal theory and physiological considerations, based particularly on the Steiner proposition and the principle that a sympathetic influence, unlike a parasympathetic influence, raises the mean heart rate, this shows that by weighting (multiplying) the measured value MLF with the mean heart rate [fH]n the above requirement is met. As it is also know from physiology that the normal range (normal sinus rhythms) of the (mean) heart rate is between 60 and min-1 the „mean" of this range, i.e. 70 min-1 is to be used as the standardised value in the above calculation. This then corresponds sufficiently to the normal heart rate value of 72 min-1 according to Schmidt and Thews [Schmidt, R F und G Thews: Physiologie des Menschen. 27th edition, Springer Berlin Heidelberg New York 1997].

The following **specifications for the spectral measured value**s including the **sympatho-vagal** balance (or simply „balance") can therefore be set – these are also used in the clue medical evaluation software:

$$M_{LF} \bullet [\frac{\overline{f_H}}{70\min^{-1}}]^2 = M_{LF}^*,$$

$$M_{HF}$$

$$\textit{Weighted balance} \quad B = \frac{M_{LF}^*}{M_{HF}}$$

or

$$\textit{Weighted balance} \quad B = \frac{M_{LF}}{M_{HF}} \bullet [\frac{\overline{f_H}}{70\min^{-1}}]^2$$

M_{LF} *- spectral measured value for the LF range*
M_{LF}^* *spectral measured value M LF weighted with the square of the mean heart rate, representing a* **measurement for sympathetic activity, stress and strain**.
M HF spectral measured value for the HF range, representing a **measurement of parasympathetic activity, relaxation and recovery (no weighting here)**
B weighted (sympatho-vagal) balance as the ratio of the LF and HF ranges multiplied with the square of the standardised mean heart rate.

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A weighting with the square of the mean heart rate thus yields the following results:

• If, for instance, M_{LF} is greater than normal, this value is significantly increased by the weighting with the square of fH in the case of a tachycardiac heart rate, resulting in $M_{LF} * (M_{LF} * M_{LF})$.

• An increased heart rate leads to a considerable disturbance in the sympatho-vagal balance (increase with the 2nd power of *f* H], which is also physiologically correct. If the relationship between the sympatho-vagal balance B and MLF/ MHF is applied as a function of the mean heart rate (**figure 11**), this behaviour is very clear.

It is evident that faster heart rates significantly increase this relationship, while frequencies less than the normal value of fH = 70 min-1 significantly reduce this effect. This completely complies with the physiological behaviour, as high heart rates activate the sympathetic nervous system and thereby stress components, while heart rates below the normal value activate the parasympathetic nervous system, thereby reducing stress levels. The following examples are given (see figure 11):

- f_H = 50 min^{-1}: a weighting reduces the relation to 0.51.

- f_H = 100 min^{-1}: The relation increases to 2.04.

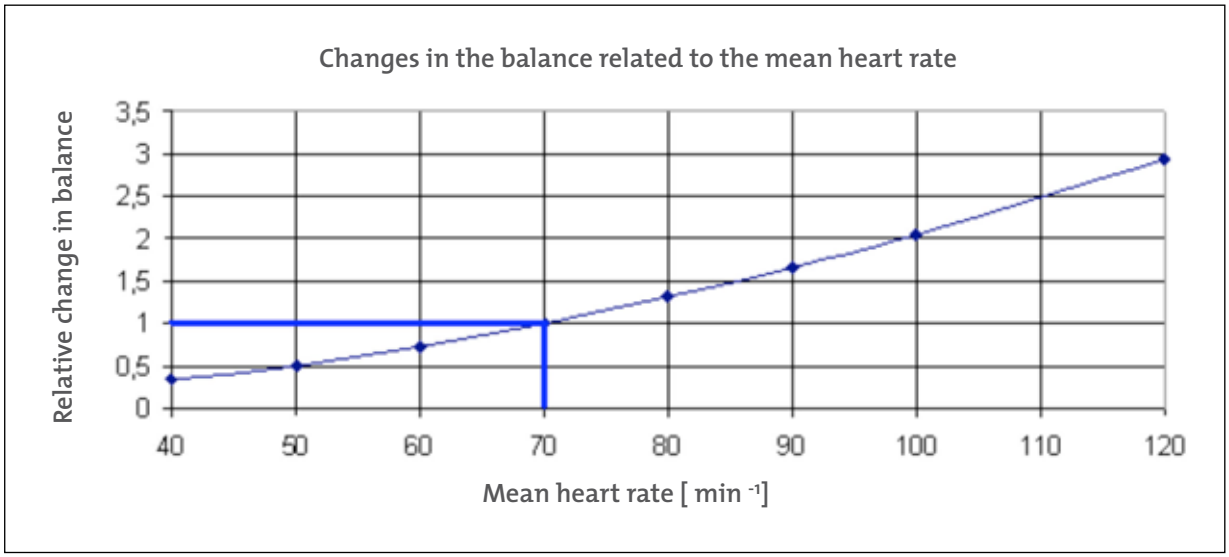

Fig. 11:
Relationship between the sympatho-vagal balance B to M_{LF}/M_{HF} as a function of the mean heart rate.
Only at a mean heart rate of 70 min-1 (defined norm) is the balance unchanged, as $M_{LF} = M_{LF}^*$ applies for the spectral measured values in this case.

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4. Examples of clinical application

4.1. Physiological function tests of reflectory vasoconstriction and hyperventilation

Figures 12 a) to e) are **practical examples** of resting ECGs in a 30 year old recumbent study subject (smoker) with 2 minutes tracing time and under the **physiological function tests of reflectory vasoconstriction and hyperventilation (deep breathing) under 6 or 10 min-1.**

In **figure 12a),** a resting ECG, the stress and relaxation measured value is considerable below the normal values, the sympatho-vagal balance B = 1.04 is within the normal range. In **12 b)**, however, there is a dramatic difference. Suddenly immersing a hand in icy water triggers a sympathetic nervous system activation wave, reducing cardiovascular microcirculation and raising the heart rate. This is clearly evident in the weighted stress value M_{LF}*, that increases four-fold with the typical frequency maximum at 0.1 Hz, while the relaxation value M_{HF} remains unchanged. The balance increases to 4.84 as an expression of the triggered sympathetic activation wave. This change is a completely normal cardiovascular response - there is no cardiovascular autonomic neuropathy.

Figures 12 c) and d) show the conditions under the physiological stress function tests with hyperventilation in the same person in a recumbent position, with values of 6 and 10 min^{-1} . The various rates lead, as expected, to a completely changed balance. At 6 min^{-1} ≡ 0.1 Hz there is a clear maximum in the LF range of the FFT spectrum, the stress value M_{LF}* increases to 5.9 and the balance also increases with a minimum recovery value of 15; however, in the hyperventilation test the results are the other way round, with values of 10 min^{-1} ≡ 0.167 Hz, i.e. in the HF range of the FFT spectrum: the balance reaches the minimum value of 0.1, with the increased recovery value of 4.4 with minimum sympathetic nervous system activity.

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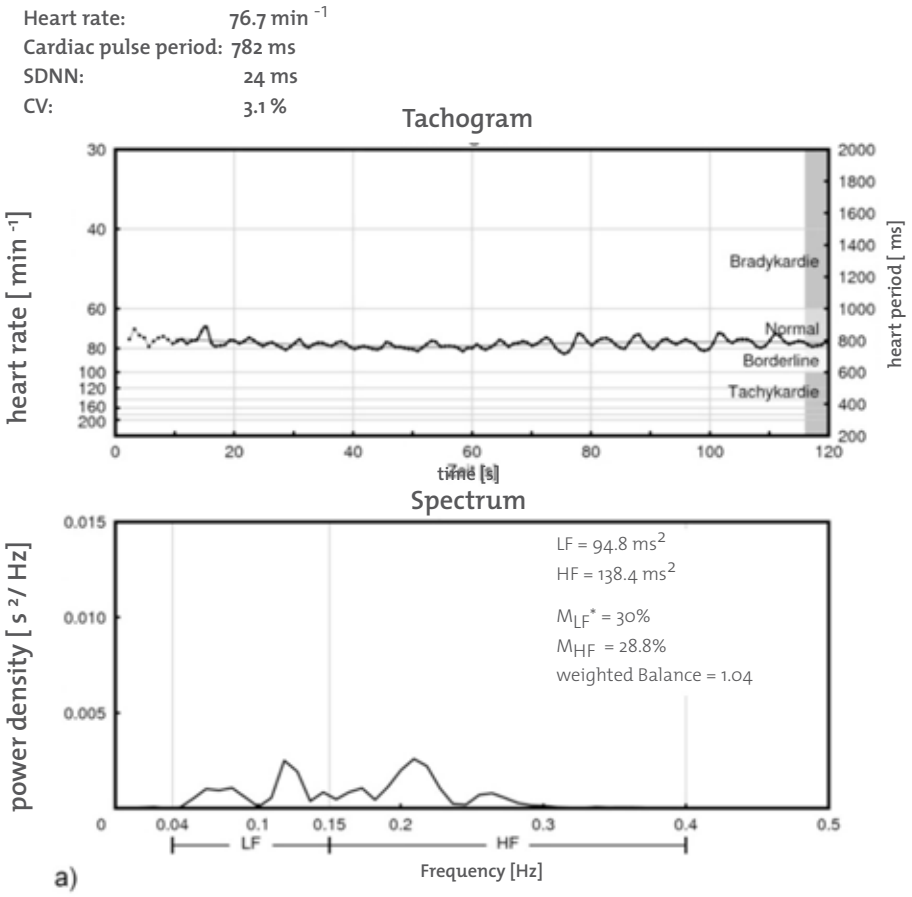

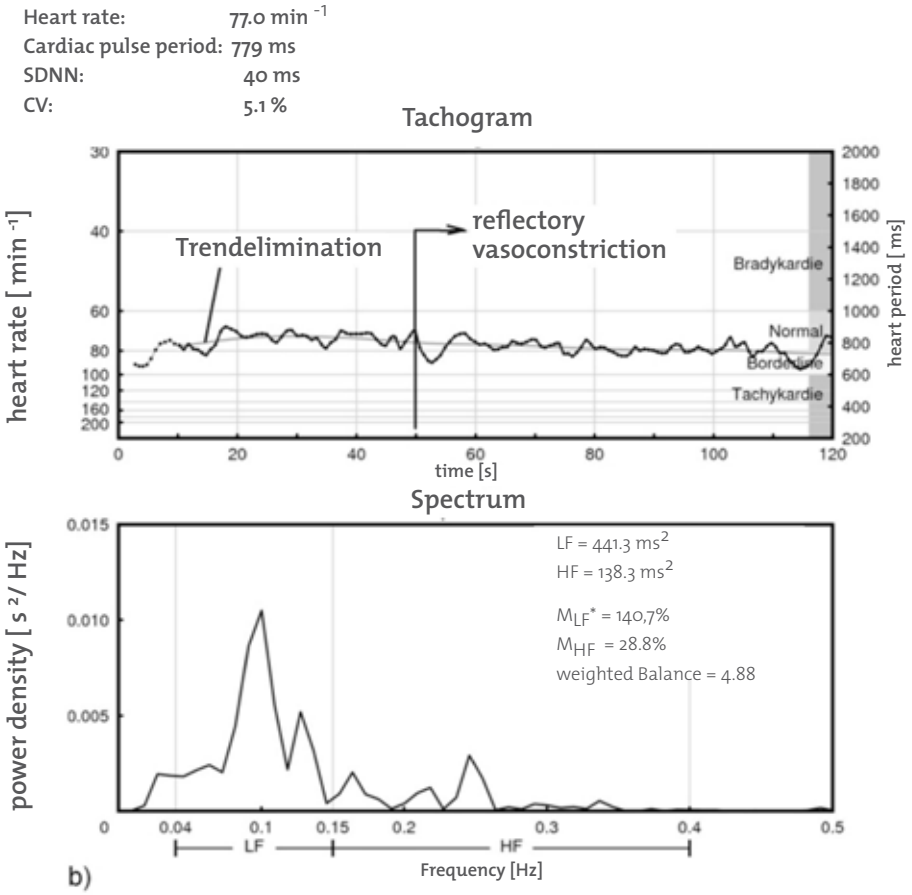

Fig. 12a and 12b: Cardiac pulse period tachograms and associated FFT spectral and cardiovascular values, calculated with **clue medical** *in a 30 year old study subject (smoker) resting in a recumbent position [a)] and reflectory vasoconstriction (passively suddenly immersing the left hand in icy water) [b)].*

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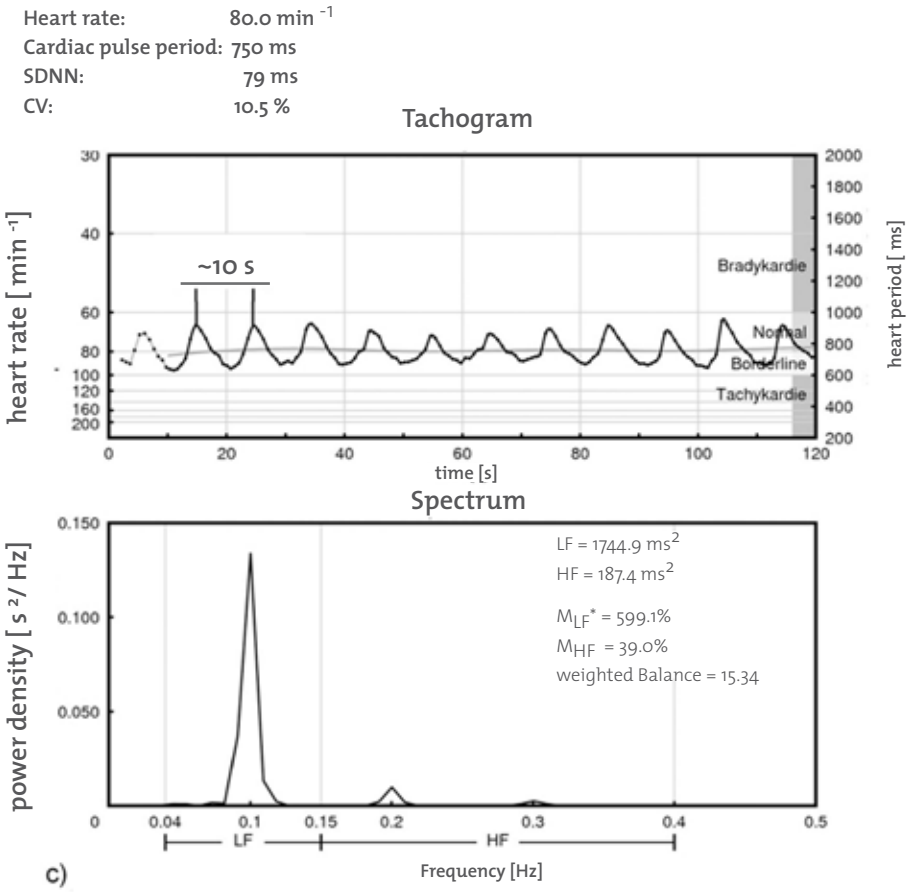

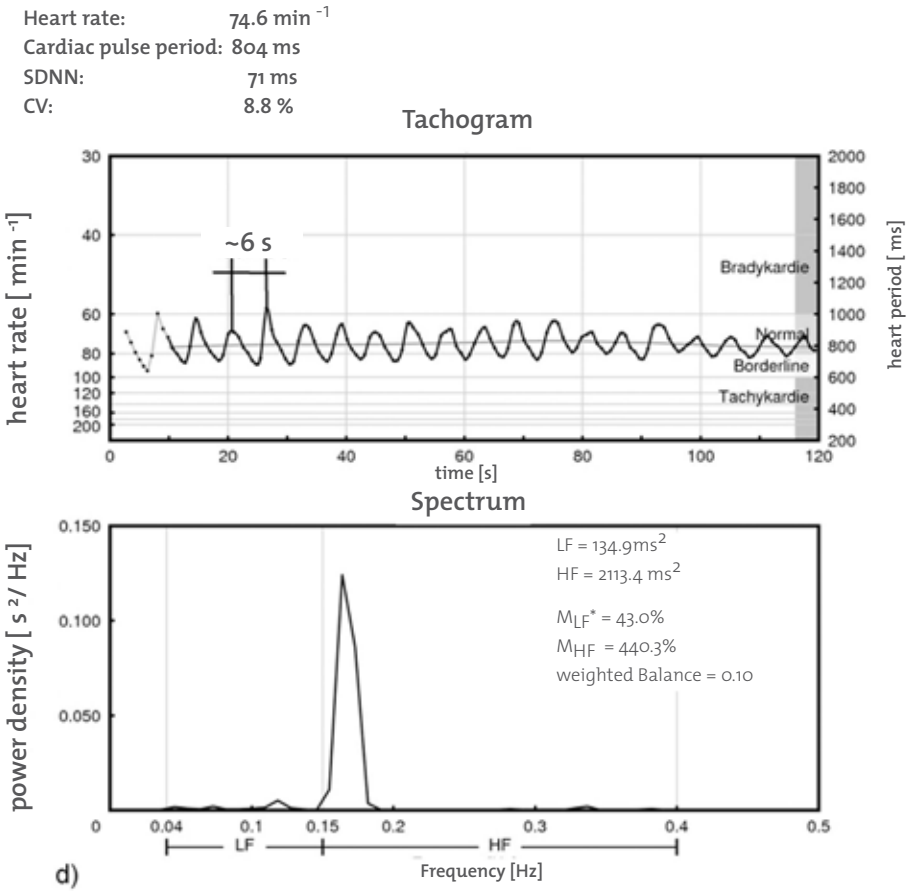

Fig. 12c and 12d: Cardiac pulse period tachograms and associated FFT spectra and cardiovascular values, calculated with **clue medical** *in the 30 year old study subject (smoker) resting in a recumbent position [a)] and with hyperventilation at 10 [c)] and 6 min-1 [d)].*

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Figure 13 shows sections of the tele-ECG from figure 12 at 6 und 10 min-1 . The various R-R intervals are clearly evident on breathing in and out, but also in the cardiovascular variables. By activating the sympathetic nervous system hyperventilation of 6 min-1 ≡ 0.1 Hz compared to 10 min-1 ≡ 0.167 Hz results in a higher frequency, shorter cardiac pulse period and a greater relative heart rate variability.

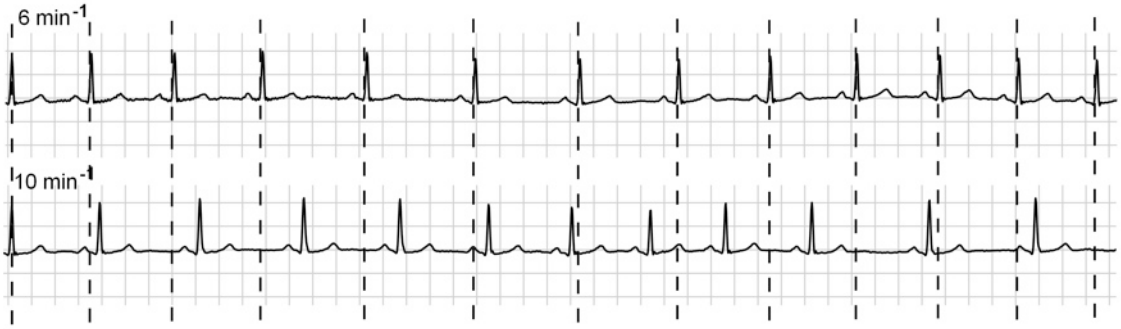

Fig. 13 extract from a tele-ECG with the study subject in a recumbent position from figures 12 c) and d) with hyperventilation of 6 and 10 min-1. There are clear differences in the R-R intervals and inhalation and expiration and in the overall cardiovascular variables (see figures 12 c) and d)].

4.2. The Ewing test

The standardised cardiovascular **Ewing test** with clue medical is carried out as follows:

- **Tracing a resting ECG (2 minutes) in a recumbent position**
- **Tracing an ECG actively standing (2 minutes)**

The changed R-R intervals during active standing are taken from the ECGs and graphically shown on the tachogram. A test of this kind is often used to identify diabetic cardiovascular autonomic neuropathy early on in diabetic patients, and to record changes by continuous readings taken at defined times. According to Ziegler [Ziegler, D., D. Claus, Th. Meinertz and F. A. Gries: Klinik, Diagnostik und Therapie der kardiovaskulären autonomen Neuropathie. Deutsches Ärzteblatt 93, H. 10, May 1996] cardiovascular autonomic neuropathy is found in some 25% of type I diabetics and in some 35% of type II diabetics and is associated with an unfavourable cardiovascular prognosis. For this reason its diagnosis has in recent years been the focus of much interest among diabetologists and cardiologist [Grohmann, G.; Krauß, M. und S. Müller: Vergleichende Untersuchungen zur autonomen kardialen Neuropathie bei Patienten mit Diabetes mellitus mit dem NIRP- und dem ProSciCard-Verfahren. PERFUSION 12; 1999: 392-408.22].

R-R-tachograms in the Ewing test [Hilz, J M et al: Autonome Störungen bei Polyneuropathien. Med Klin 1998;93:533-40]:
If you stand up from a recumbent position, the pulse rate increases, normally reaching a peak at about the 15th heart beat. The heart rate then falls, reaching its maximum at about the 30th heart beat after standing up. The resulting ratio of the associated R-R intervals, known as the
30:15 – ratio, is used for assessment purposes. Various authors recommend using the range between the 20th and 40th beat for the longest and between the 5th and 25th beat for the shortest R-R interval after standing up, rather than the less exact 15th or 30th heart beat, because of the possible spread of results. If there is an increase in the heart rate in the form of a temporal step function when actively standing up, as shown the frequency segments in the range below 0.15 Hz increase. In other words, the sympathetic innervation of the heart is increased and thereby also the associated cardiac spectrum measured value MLF*.

Figure 14 shows this scenario:
Figure **14 a)** recumbent 25 year old person in good health,
Figure **14 b)** standing up from a recumbent position (Ewing test).

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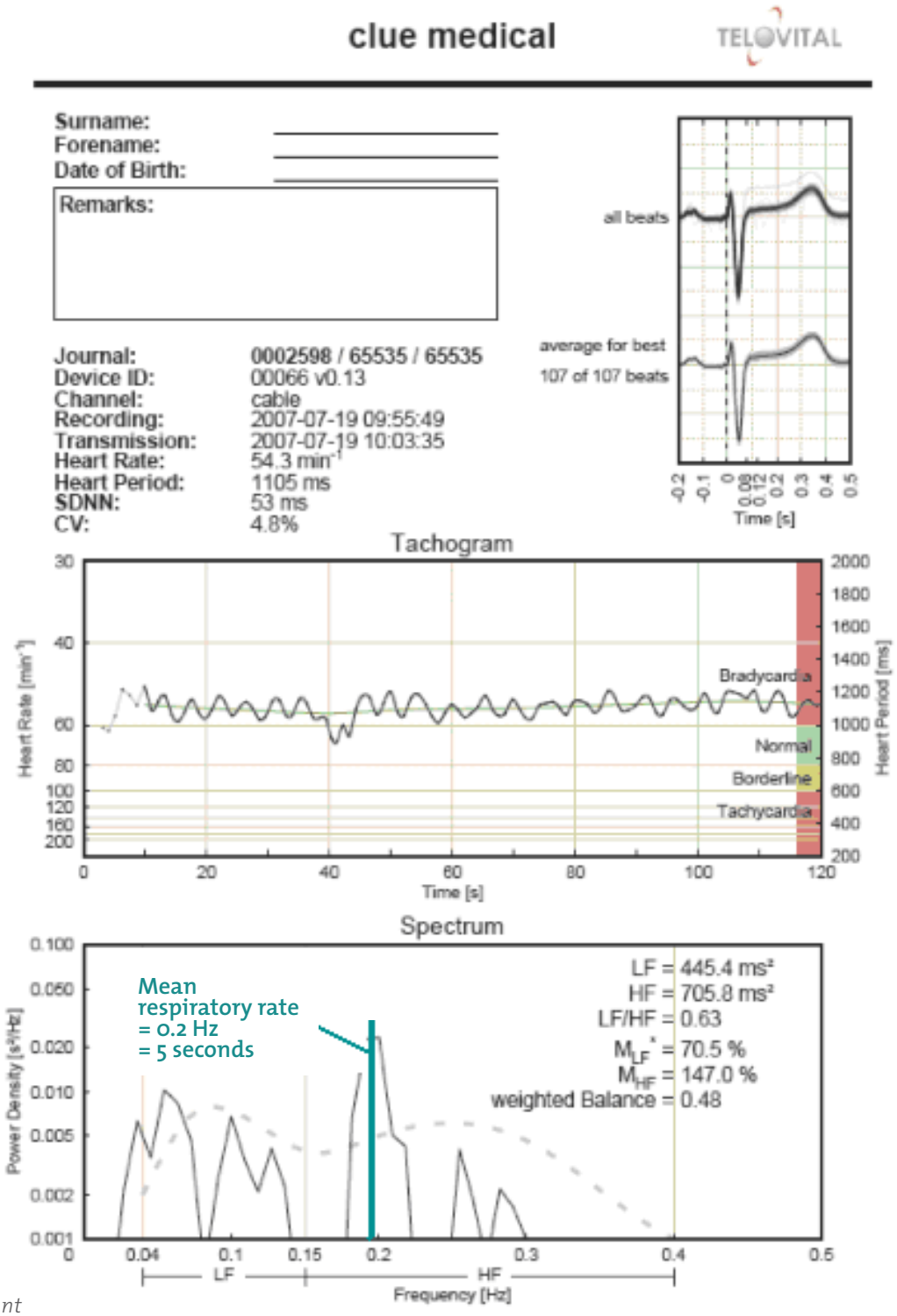

Fig. 14a cardiovascular condition of a recumbent 25 year old in good health also showing the mean respiratory frequency of approximately 0.2 Hz. [Note: - - - - derived mean FFT curve in an approximately 25 year old person in good health]

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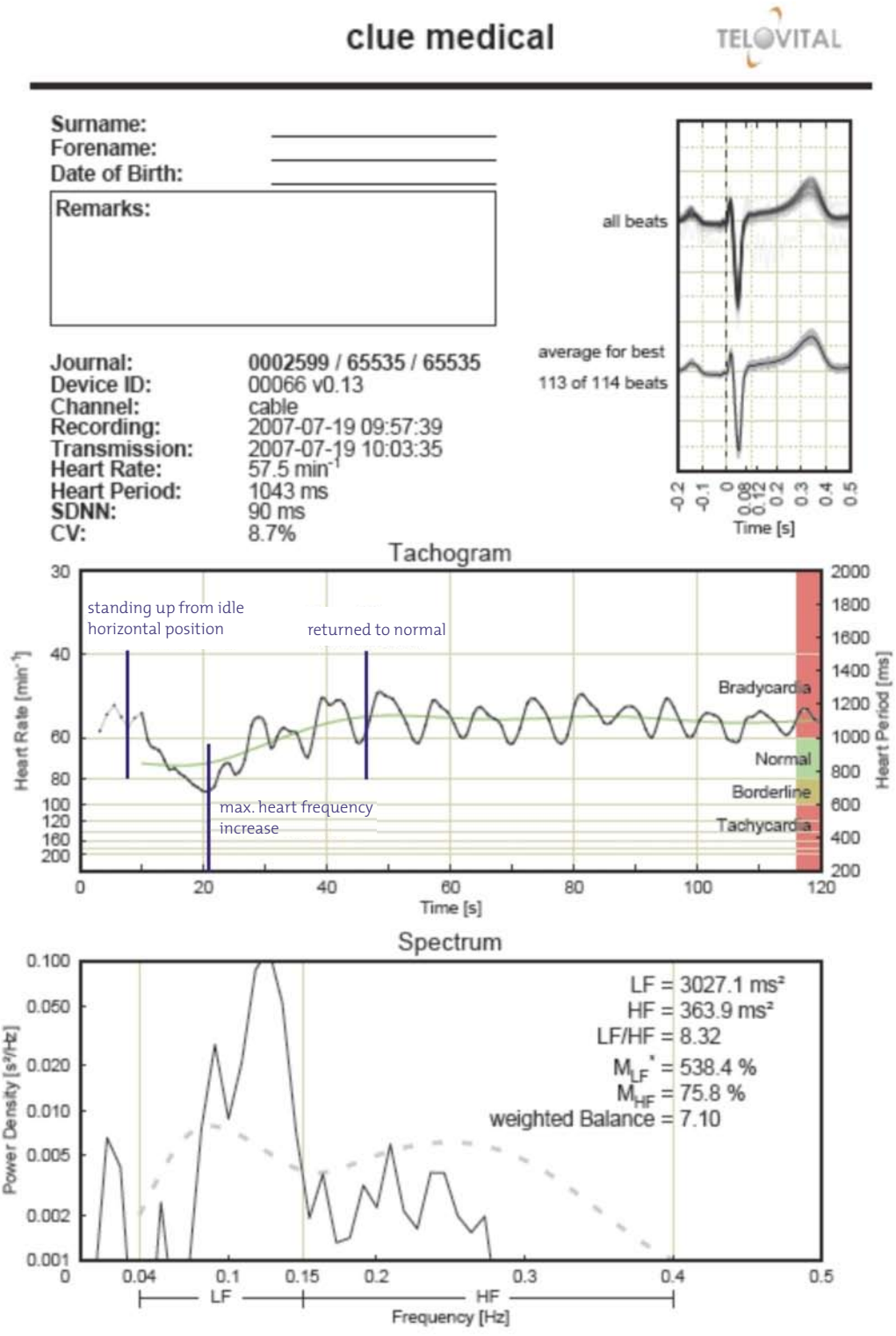

Fig. 14b
Ewing test in the test person in figure 14 a). There is an increase in the heart rate as soon as the person stands up until about the 15th heartbeat, then the heart rate returns to normal, i.e. the initial heart rate is reached. This is the normal, healthy response (ideal case). [Note: - - - - derived mean FFT curve in an approximately 25 year old person in good health]

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While the age-related normal values for SDNN and CV for this study subject can be calculated from 14 a), this can also be estimated for the vegetative component of the cardiovascular system. A weighted balance of 0.48 indicates a normal response (ideal = 1). The step function in the Ewing test (figure 14b) also shows „a normal response", both in the increased heart rate after standing up and its return to normal between 40 and 50 s. In a comparison of the introduced spectrum measured values and the weighted balance for lying down and standing up, a normal response is clear: **significant increase in M_{LF}* and in the balance with a drop in MHF on standing up.** There is no indication here of the start of a diabetic cardiovascular autonomic neuropathy and the mean cardiac frequency is in the bradycardiac range.

4.3 Cardiovascular parameter changes in a 26 year old sporty, healthy man before and after 60 minutes fitness training „Spinning"

Figure 15 a) shows the cardiovascular parameters in a 26 year old sporty, healthy male, **Figure 15 b)** shows the same man 10 minutes after a 60 minute Spinning session. Parameter comparison:

– *Before spinning:*

- Heart rate bradycardiac,
- high heart rate variability,
- value for M_{HF} (Vagal tone) very high,
- M_{LF}* as an indication for sympathetic nervous system activity, stress and strain low, but still within normal range,
- weighted balance only 0.19 (no vegetative balance)

– *After spinning:*

- heart rate has increased,
- heart rate variability a little lower
- M_{HF} reduces (mean normal value),
- M_{LF}* as an indication for sympathetic nervous system activity and strain has almost doubled compared with the „before spinning" value,
- weighted balance has normalised (vegetative cardiovascular balance).

Further tests need to be carried out to ascertain to what extent these results can be generalised. This example is only designed to illustrate that changes in cardiovascular parameters can also be seen with **clue medical,** even with high impact sports. It also appears to be possible to assess the training status with the presented cardiovascular parameters.

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Journal:	0001409 / 0 / 0
Device ID:	00088 v0.5
Channel:	cable
Recording:	2007-03-01 17:15:18
Transmission:	2007-03-01 17:23:24
Heart Rate:	54.4 min^{-1}
Heart Period:	1102 ms
SDNN:	67 ms
CV:	6.1%

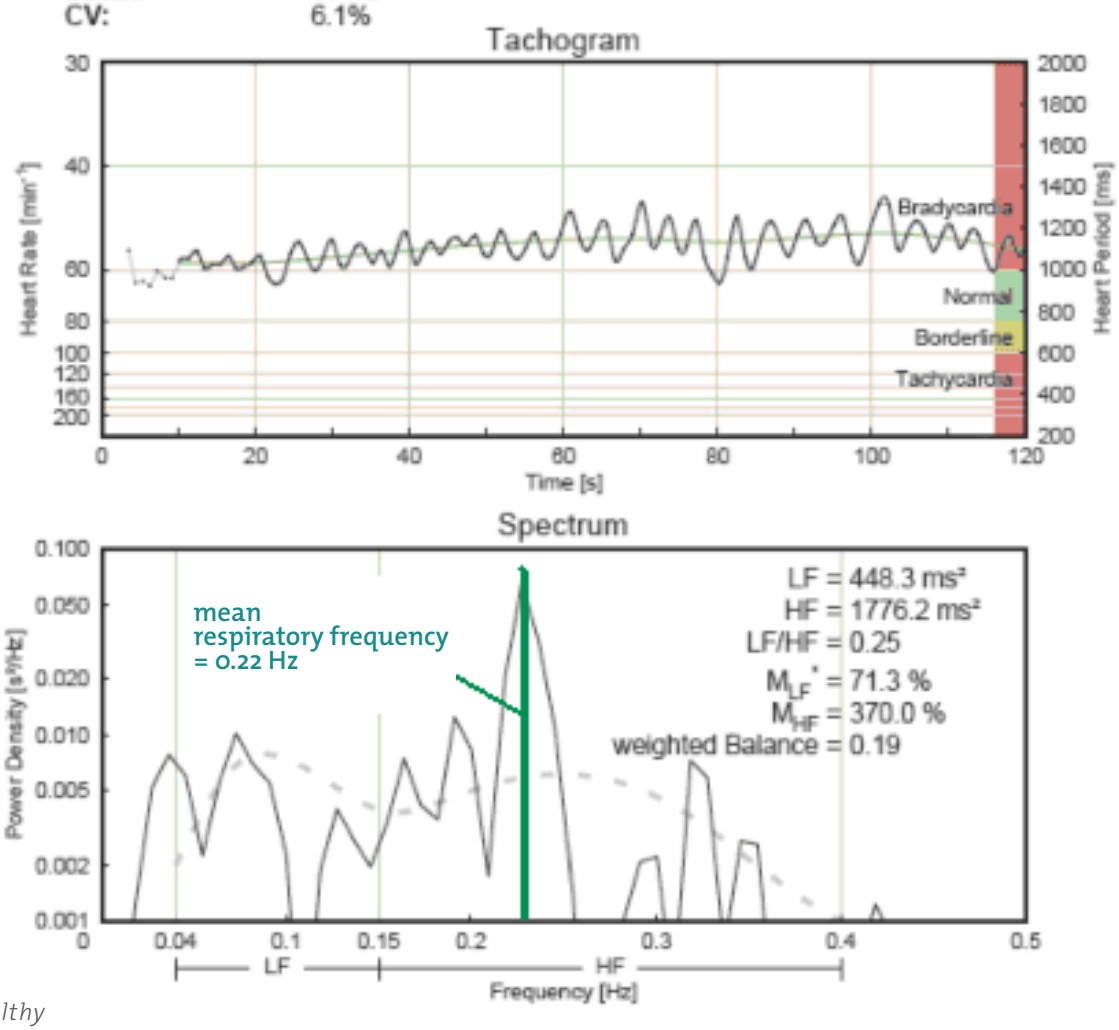

Fig. 15a:
26 year old sporty, healthy male before spinning
[Note: - - - - derived mean FFT curve in an approximately 25 year old person in good health]

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Surname:
Forename:
Date of Birth:

Remarks:

Journal:	0001418 / 0 / 0
Device ID:	00088 v0.5
Channel:	cable
Recording:	2007-03-01 18:46:57
Transmission:	2007-03-01 18:54:22
Heart Rate:	60.7 min^{-1}
Heart Period:	989 ms
SDNN:	53 ms
CV:	5.3%

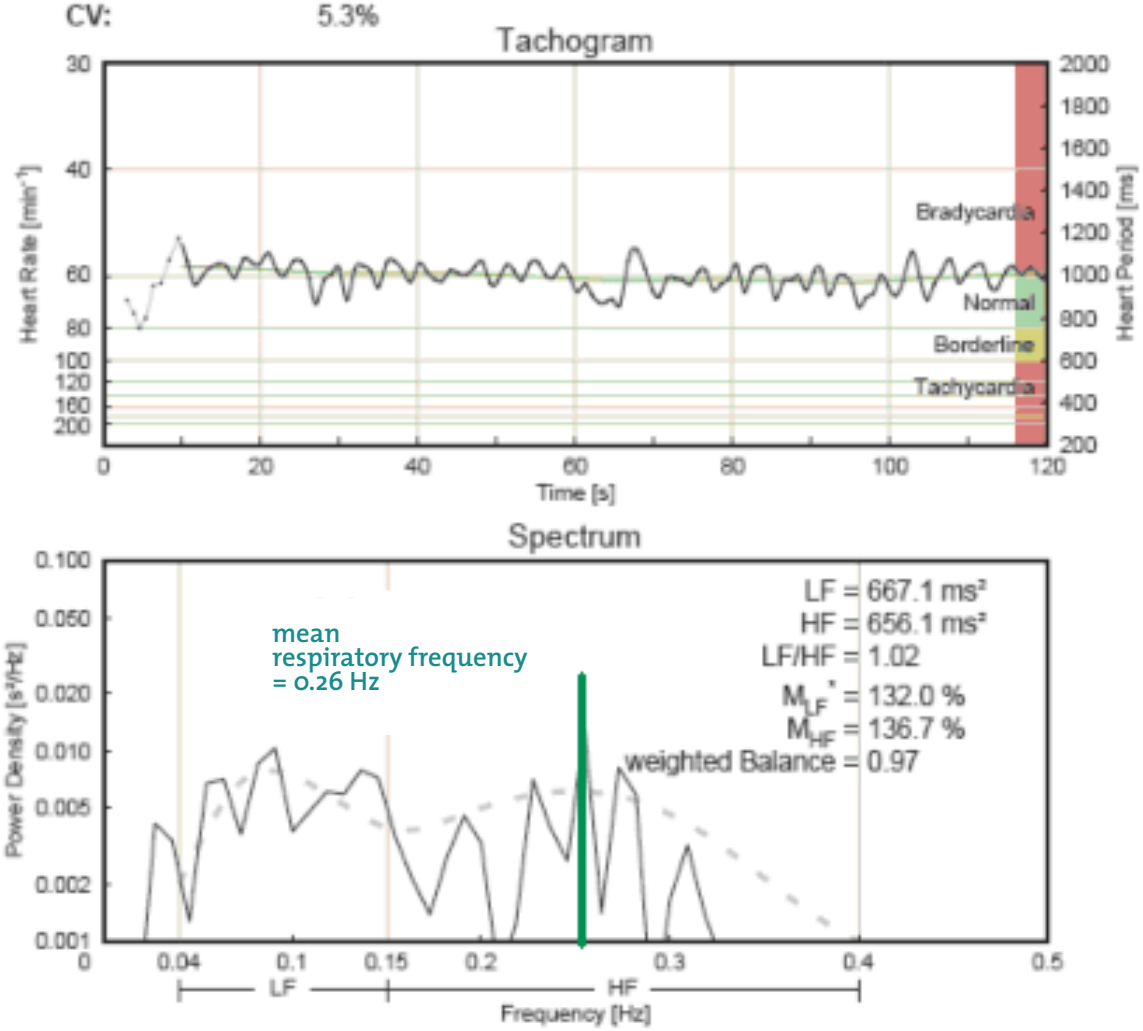

Fig. 15b:
26 year old sporty, healthy male after spinning
[Note: - - - - derived mean FFT curve in an approximately 25 year old person in good health]

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5. Spectrum measured values and FFT spectrum: Cardiovascular parameter changes with (physical) therapy in a 55 year old study subject

clue medical was used to establish characteristic functions and values in a 55 year old relaxed and seated study subject, as shown in **figure 16 a).** After a (physical) cardiovascular thereapy the cardiovascular parameters were re-recorded **(figure 16 b).**

General results (see figure 16):

- the heart rate in the known normal range of 60 ... 80 min-1 is reduced from 80.8 to 78.7 min-1 ,
- the absolute heart rate variability SDNN increases from 15 to 21 ms,
- the relative heart rate variability CV also increases from 2 to 2.8%.

In a comparison of the results of the heart rate variability in this test person with the age-dependent cardiovascular threshold normal values as shown in figure 6, it is evident that the results were significantly below the lower limit for the normal range before the stimulation, and that the results improved significantly afterwards.
The tachogram of the cardiac pulse period before the treatment (figure 16 a) shows that a there is a respiratory connection (respiratory sinus arrhythmia), leading to the normal values for the heart rate variability, but that long-wave, irregular changes are also apparent in the tachogram. A respiratory sinus arrhythmia in the tachogram becomes more and more extreme after the stimulation, leading to higher heart rate variability.

Special results

An analysis of the FFT spectra derived from the cardiac pulse periods in figure 16 allows the above qualitative statements on the respiratory sinus arrhythmia can be quantified. It is evident that there is a dominant frequency component in this study subject in the LF range of approximately 0.06 Hz before the stimulation, and that the maximum HF frequency component of approximately 0.17 Hz, an expression of respiratory sinus arrhythmia, is less pronounced. This changes dramatically with the stimulation: the amplitude of the maximum LF frequency components, at approximately 0.07 Hz, is minimal compared with the amplitude of the respiratory frequency of (only) 0.14 Hz, so that in the tachogram for the cardiac cycle the respiratory sinus arrhythmia is dominant and the heart rate variability has clear normal values [note: the mean respiratory frequency fell after stimulation to 0.14 Hz ≡ 7.1 s. This is virtually on the defined LF-HF frequency limit].

The clue medical software allows the integral surface of the LF and HF ranges to be determined from the FFT spectra. However, as figure 16 shows, for this application there are no significant surface differences before and after the stimulation and the actual information for this case is evidently in the distinctive frequency lines. **For this reason both variants should be used for application cases of this kind, to ensure a comprehensive cardiovascular assessment.**

Appendix 1 shows the mean values of cardiovascular parameters, defined with clue medical from a group of 98 subjects with a healthy cardiovascular system with an average age of 25 ± 5.

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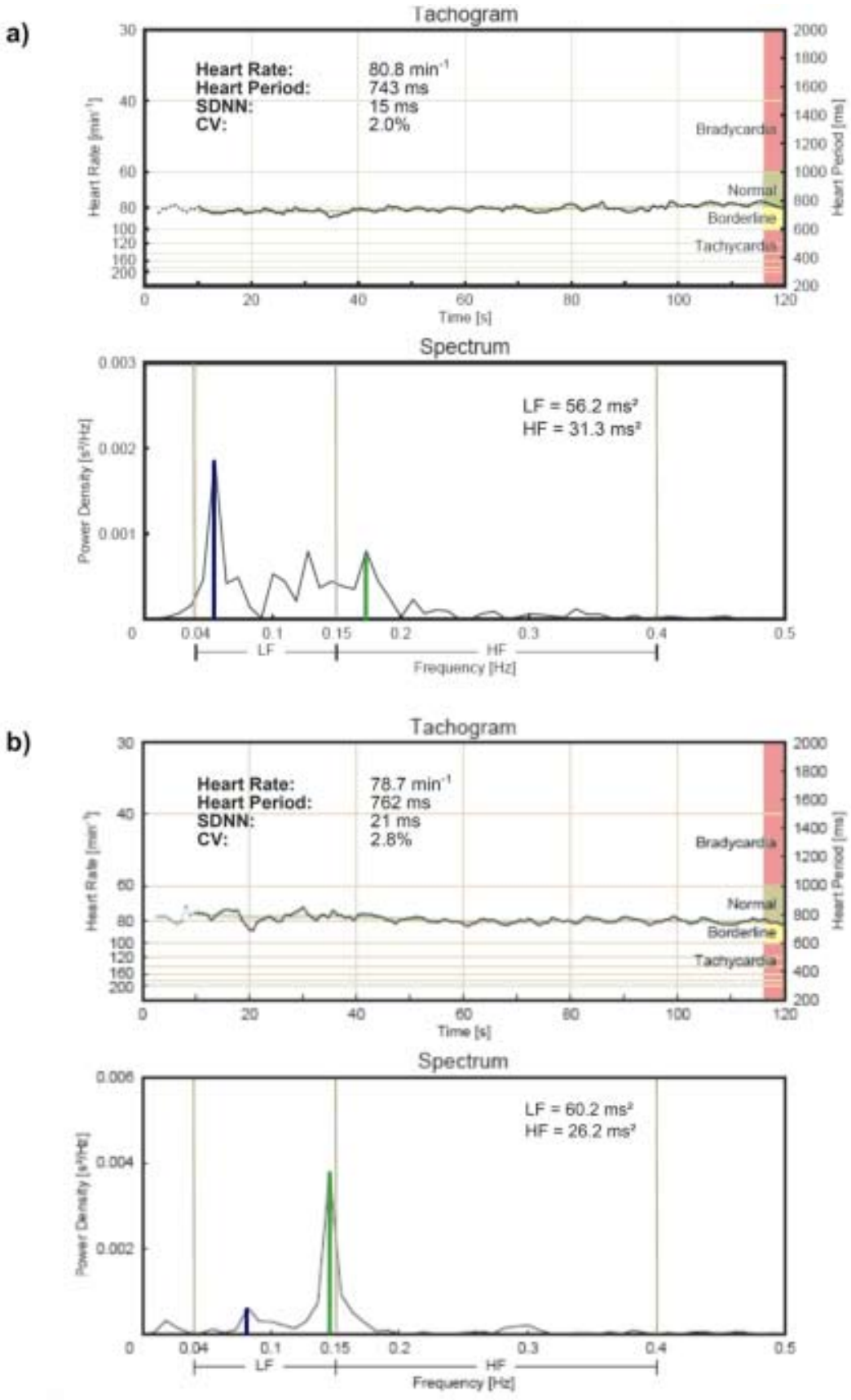

Fig. 16:
Cardiovascular specific functions, derived with **clue medical,** *in a 55 year old test subject before [a)] and after [b)] physical therapy*

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6. General Information

There is an ever increasing number of scientific publications concerning **„heart rate variability“,** with some 40,000 hits in German literature alone currently available on the internet. A summary has been provided in **appendix 2;** one very comprehensive and scientifically sophisticated paper is the dissertation by Horn [Horn, A: Diagnostik der Herzfrequenzvariabilität in der Sportmedizin - Rahmenbedingungen und methodische Grundlagen. Diss, Fakultät für Sportwissenschaft, Ruhr-Universität Bochum 2003], which is listed in the bibliography.

Appendix 1: Mean values for cardiovascular parameters, derived from a group of 98 test subjects with a healthy cardiovascular system with an average age of 25 ± 5 years with clue medical

The following mean values of the cardiovascular parameters were taken from two tracings each on a group of 98 study subjects with healthy cardiovascular systems, [mean age 25 ± 5 years] carried out at the Institut für Sportwissenschaften der Johann-Wolfgang-Goethe- Universität Frankfurt in a study led by Prof. Dr. D. Schmidtbleicher and are used as the „normal values“ for a group of this kind, the **clue medical** provides for doctors as a guideline.

Code	Name of the parameter	Values
	mean heart rate	51 ... **61,3** ... 77 [min-1]
SDNN	absolute heart rate variability	26 .. **53** ...106 ms
CV	Variation coefficient = relative heart rate variablity	2.9 ... **5.5** ... 10.3 %
LF	LF-surface	90 ... **420** ... 2000 ms2
HF	HF-surface	95 ... **525** ... 2900 ms2
VHF	VHF-surface	2 ... **17.4** ...80 ms2
M_{LF} *	spectral measured value MLF weighted with the square of the mean heart rate	23 ... **100** ... 450 %
M_{HF}	spectral measured unit for the HF frequency range	18 ... **100** ... 550 %
B*	weighted balance	0.2 ... **1** ... 5
LF/HF	„simple“ balance as the ratio of LF- to HF-surface	0.19 ... **0.81** ... 3.4

Table: „Normal ranges to be used as a guide“ for cardiovascular parameters, derived from 98 study subjects with a healthy cardiovascular system [mean age 25 ± 5].

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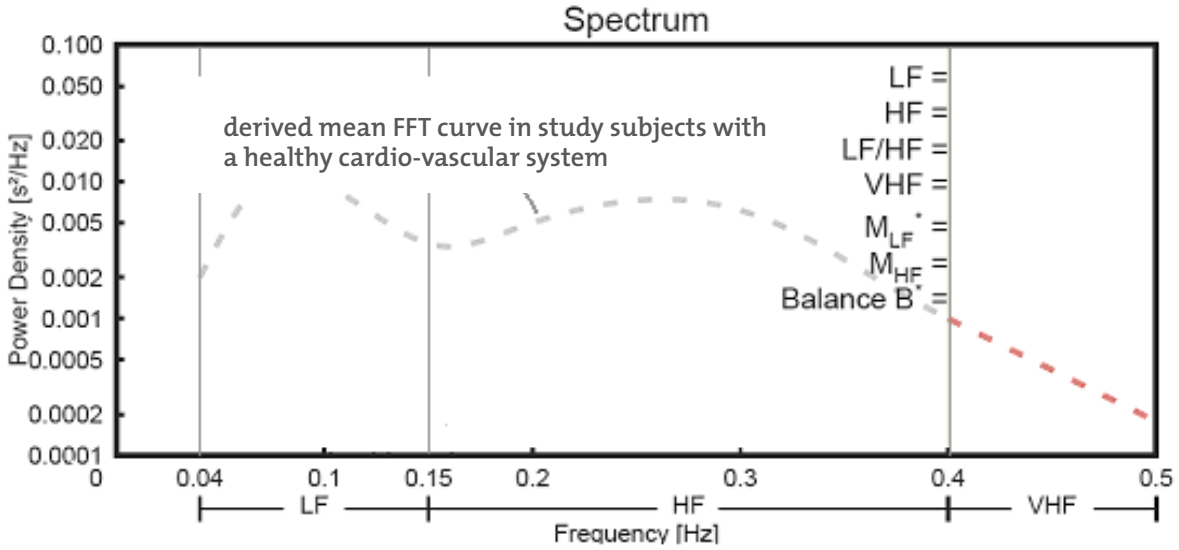
Comments on normal cardiovascular values:

Due to non-linearities in the cardiovascular system the question as to what are the „standard values or ranges“ arises, as in this case standard values or ranges are always fixed to a „reference point“. The sport scientist A. Horn [Horn, A: Diagnostik der Herzfrequenzvariabilität in der Sportmedizin - Rahmenbedingungen und methodische Grundlagen. Diss, Fakultät für Sportwissenschaft, Ruhr-Universität Bochum 2003] also examines this problem in her dissertation and reaches the following conculsion: „It is questionable whether standard values can be defined“. This is a very good point due to the non-linearity, so that setting cardiovascular „standard parameters“ is also practically impossible. They always require linearity. It is, however, possible to define „guideline standard ranges“ involving the mean age (see above table) to define **„minimum“ values („lower limit of heart rate variabilities“, s**ee page 11), where a system of this kind may become instable.



clue-medical-*surface „FFT-spectrum with logarithmic power density - scale“ including derived cardiovascular parameters and a mean FFT curve in study subjects with a healthy cardio-vascular system (- - -) as a guideline comparison*

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