

Validity trial
of the medical measuring instruments
vicardio 1.0.4 and cardioscan CS-3 1.0

1 Aim of the trial

The medical measurement devices vicardio 1.0.4 and cardioscan CS-3 1.0 allow the measurement of the excitation phase of the heart, and describe and graphically display the data of a defined stress value. By determining the stress value possible deviations of the excitation phase can be detected at an early stage and indicators for potentially critical deviations caused by an emerging cardiovascular illness can be given. vicardio is intended for use by doctors; cardioscan is principally intended for lay use (e.g. fitness and/or wellness). Both devices have additional functions that will not be examined closely here.

The recording of the excitation phase is made via a standard resting electrocardiogram. The information contained in the electrical signals of the heart are, on the one hand, graphically and numerically displayed and, on the other, analysed with the help of a stored algorithm and finally graphically presented as an electrocardioprotrait (ECP).

The stress value displayed is derived from stored algorithms that take into account the possible deviations in the autonomous regulations of the heart. Amongst others via the various parameters of heart variability that are weighted in accordance with their significance.

The trial will attempt to clarify whether the analysis of the electrocardiogram and the description of the stress value are valid. For this comparison measurements were taken using a standard ECG device and both the vicardio 1.0.4 and the cardioscan CS-3 1.0 from a total of thirty subjects aged over 18 years old, as well as with questionnaires on their subjective appraisal of their own state of health.

The following exclusion criteria were defined for the trial group:

- under 18 years of age
- Existence of a pregnancy
- Presence of a heart pacemaker

2 Methodology

2.1 Trial design

The planned trial comprised the collection of person-specific data via a standardised questionnaire, the actual validity measurements as well as blood pressure measurements.

2.2 Trial group

30 people took part in the trial (see table 1)

Table 1: Anthropometric data of the trial group

	n	Age	Height	Weight
In total	30	26.4 ± 9.4	175.0 ± 8.3	68.1 ± 11.1

2.3 Course of the trial

2.3.1 Questionnaire on the concise medical history and compilation of general state of health

Within the questionnaire, alongside the obligatory anthropometric items, information was collected on existing cardiovascular illnesses as well as external, internal and constitutional risk factors, physical activity in the previous 4 weeks and nutrition over the previous two days.

The health-related quality of life of the test subjects was enquired using the standardised SF-36 questionnaire on the general state of health. The SF-36 comprises 8 dimensions, which can be classified conceptually as "physical health" and "mental health": physical functional capability, physical role function, physical pain, general perception of health, vitality, social functional capability, emotional role function and mental well-being.

2.3.2 Validity trial and blood pressure measurement

The validity trial included a subsequent measurement of the ECG using the *vicardio 1.0.4* and *cardioscan CS-3 1.0* as well as a resting ECG recording (3-lead ECG) over two minutes and a beat-to-beat recording of the heart rate under standardised conditions (same examiner, same room). A simultaneous measurement of the ECG lead, as has been done in previous trials, was not possible due to the mutual interference of the deviations. Before each measurement there was a 10-minute rest phase, lying down; immediately after the measurement the blood pressure was measured using a sphygmomanometer.

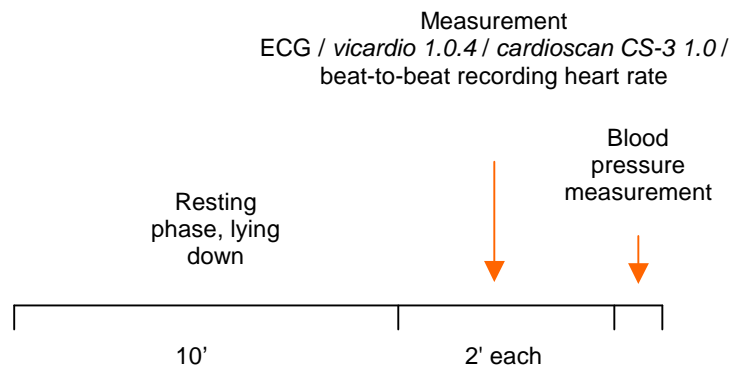


Fig. 1: Course of the validity trial

2.4 Measurement devices used

The following measurement devices were used during the trial:

- 12-lead ECG device vicardio 1.0.4, E/L/T Germany (recording of 3 extremity leads as per Einthoven)
- 1-lead ECG device cardioscan CS-3 1.0, E/L/T Germany
- 12-lead ECG device Cardiovit AT-60, Schiller Switzerland (recording of 3 extremity leads as per Einthoven)
- Automatic sphygmomanometer BOSO carat, Bosch & Sohn, Germany

2.5 Data evaluation

The following data and parameters extracted from the ECG recordings were used in the statistical evaluation:

- Heart rate (min^{-1})
- PQ interval (ms)
- QRS duration (ms)
- QT interval (ms)
- QTc interval (ms) (only vicardio 1.0.4)
- Horizontal ST segment deviation
- Stress grade / heart condition grade (vicardio 1.0.4 and cardioscan CS-3 1.0)
- Test-specific results from the SF-36 questionnaire
 - Physical functional capability
 - The degree to which the state of health affects physical activities such as self-sufficiency, walking, climbing stairs, bending, lifting and medium or strenuous activity
 - Physical role function
 - The degree to which the state of health affects work or other daily activities, e.g. achieving less than usual, restriction in the type of activities or difficulties carrying out certain activities
 - Physical pain
 - Degree of pain and influence of pain on normal work both at home and away from home
 - General perception of health
 - Personal assessment of health, including current state of health, future expectations and resilience

- Vitality
 - Full of energy and enthusiasm versus tired and worn out
- Social functional capability
 - Degree to which physical health or emotional problems affect normal social activities
- Emotional role function
 - Degree to which emotional problems affect work or other daily activities; among other things spending less time working, doing less or not as carefully as usual
- Mental well-being
 - General mental health, including depression, worries, emotional and behaviour-related control, general positive temper
- Comparison of state of health
 - Comparison of state of health with age or sex-specific norm groups

The data evaluation was carried out with the software program SPSS 12.0. In accordance with the scale level and the selection of attributes, various statistical tests were drawn on for descriptive and inference statistics.

3 Results

3.1 Comparison vicardio 1.0.4 and Cardiovit AT-60

The comparison of the ECG revealed average differences between the selected parameters of between -4ms (PQ interval) and 1 ms (QTc interval) (see fig. 2 and table 2).

In the correlation calculation all parameters showed a high correlation ($r = 0.744 - 0.962$) between the measured values from the vicardio 1.0.4 and the Cardiovit AT-60 (see fig. 3)

Table 2: Median values, standard deviations, minimum, maximum and 25, 50 and 75 percentiles of the differences between the ECG data from the vicardio 1.0.4 and the Cardiovit AT-60

	1_diff_hf	1_diff_pq	1_diff_qrs	1_diff_qt	1_diff_qtc
N	29	29	29	29	29
Median value	-,14	-4,45	-1,07	-2,38	,69
Standard dev.	2.57	8.26	6.15	28.01	29.05
Minimum	-4.00	-22.00	-12.00	-34.00	-43.00
Maximum	5.00	12.00	9.00	83.00	79.00
Percentile	25	-2.00	-10.00	-6.50	-19.50
	50	-1.00	-3.00	-2.00	-11.00
	75	2.00	1.00	4.50	10.50

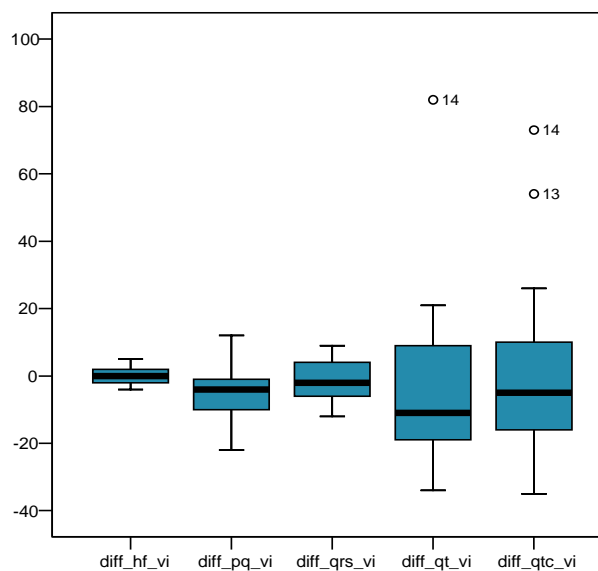


Fig. 2: Median values, standard deviations, 25 and 75 percentiles as well as outliers of the differences between the ECG data from the vicardio 1.0.4 and the Cardiovit AT-60

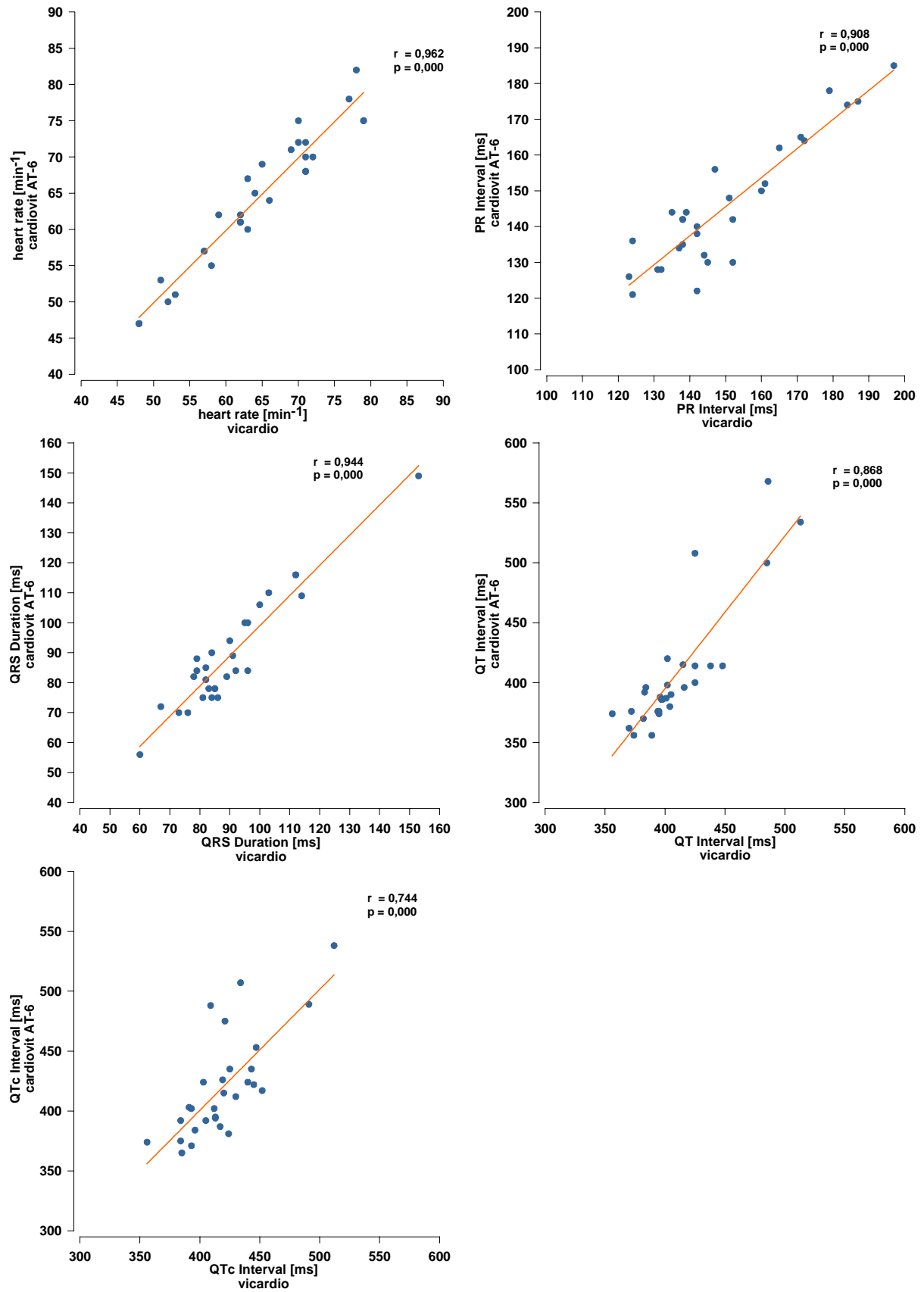


Fig. 3: Correlation between the selected ECG parameters of the vicardio 1.0.4 and the Cardiovit AT-60

Whereby $p \leq 0.05$ is significant, $p \leq 0.01$ is highly significant, $p \leq 0.00$ is most significant

ST segment changes (elevation or depression) for the vicardio 1.0.4 were shown in the comment field as the elevation or depression of a lead in cases of deviation from the isoelectrical line above 0.10mV. Therefore results depicted below show an allocation of the values of the Cardiovit AT-60 to an indication of an ST elevation or depression of the vicardio 1.0.4 respectively. In lead I and II there were 5 ST elevations in total that were also shown by the vicardio (see fig. 4).

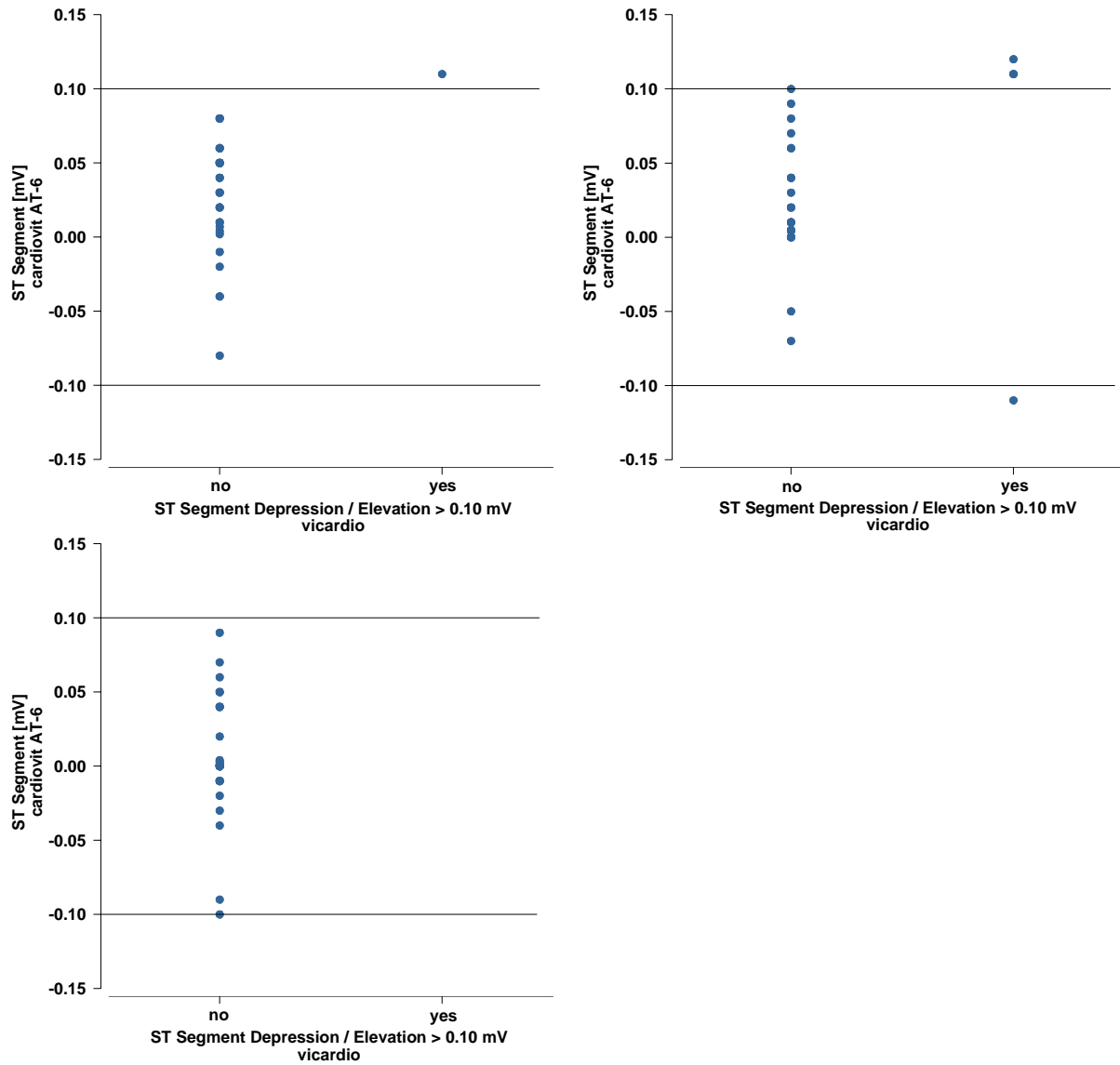


Fig. 4: Correlation between the measured deviations of the ST segments of the vicardio 1.0.4 and the Cardiovit AT-60

3.2 Comparison of cardioscan CS-3 and Cardiovit AT-60

The comparison of the ECG revealed average differences between the selected parameters of between -18 ms (QT time) and 4 ms (QRS interval) (see fig. 5 and table 3).

In the correlation calculation all parameters showed a medium to high correlation ($r = 0.642 - 0.950$) between the measured values from the cardioscan CS-3 1.0 and the Cardiovit AT-60 (see fig. 6)

Table 3: Median values, standard deviations, minimum, maximum and 25, 50 and 75 percentiles of the differences between the ECG data from the cardioscan CS-3 1.0 and the Cardiovit AT-60

	1_diff_hf	1_diff_pq	1_diff_qrs	1_diff_qt
N	29	27	29	27
Median value	-1.14	-3.30	4.28	-18.05
Standard dev.	2.84	10.92	9.21	21.37
Minimum	-6.00	-22.00	-13.00	-68.00
Maximum	4.00	12.00	21.00	14.00
Percentile 25	-3.00	-14.00	-1.50	-27.50
50	-1.00	-2.00	4.00	-17.00
75	1.00	7.00	9.50	-0.75

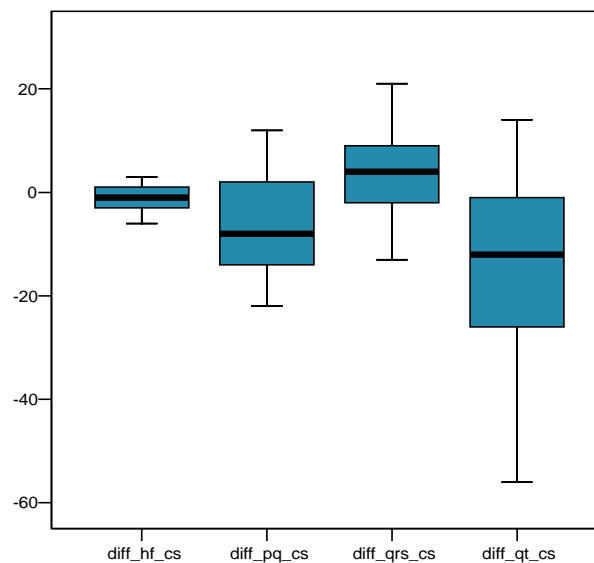


Fig. 5: Median values, standard deviations, 25 and 75 percentiles as well as outliers of the differences between the ECG data from the cardioscan CS-3 1.0 and the Cardiovit AT-60

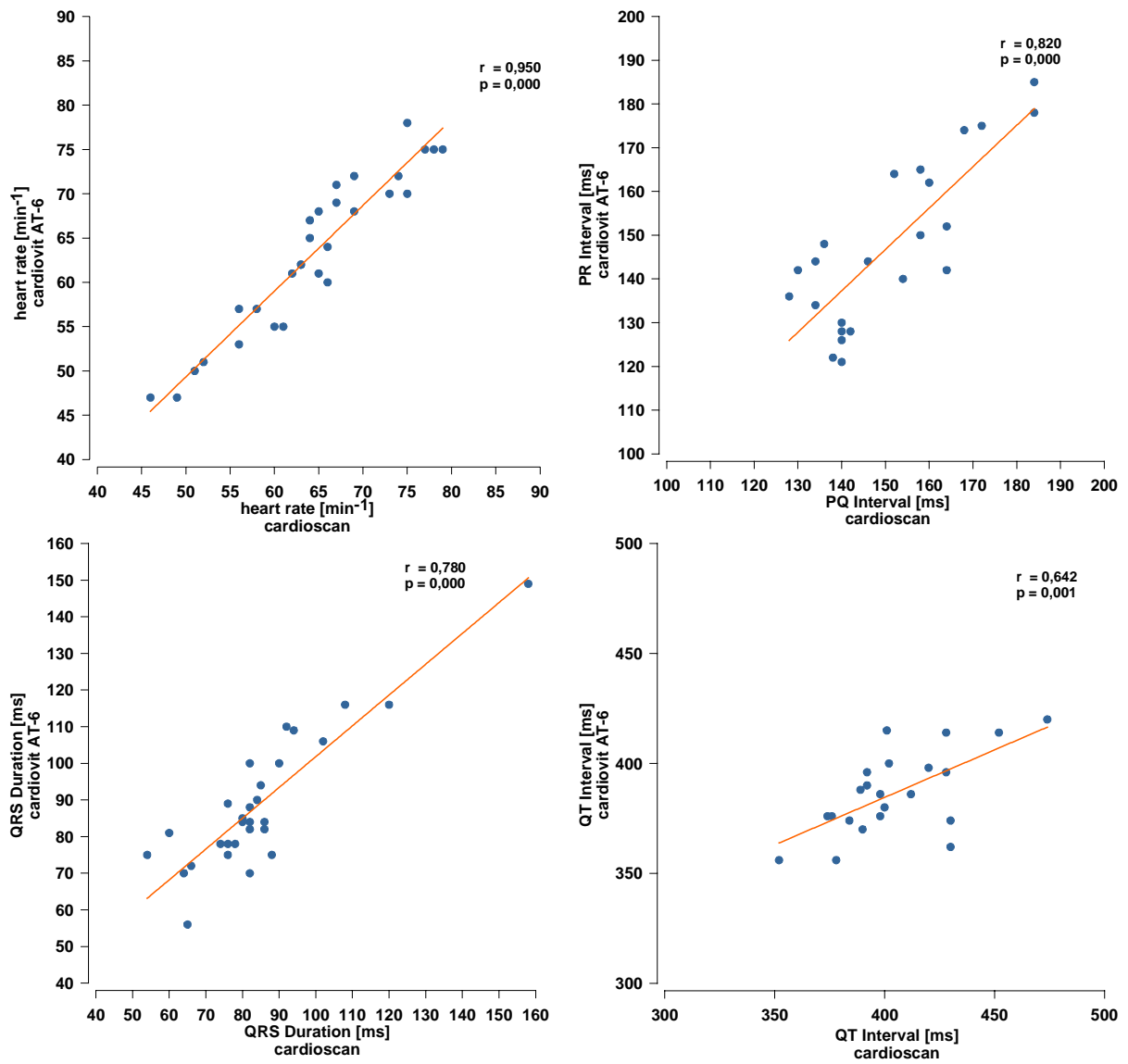


Fig. 6: Correlation between the selected ECG parameters of the cardioscan CS-3 1.0 and the Cardiovit AT-60

Whereby $p \leq 0.05$ is significant, $p \leq 0.01$ is highly significant, $p \leq 0.00$ is most significant

The comparison of the ST segment changes showed a high correlation ($r = 0.845$) between the cardioscan CS-3 1.0 and the Cardiovit AT-60 (see fig. 7).

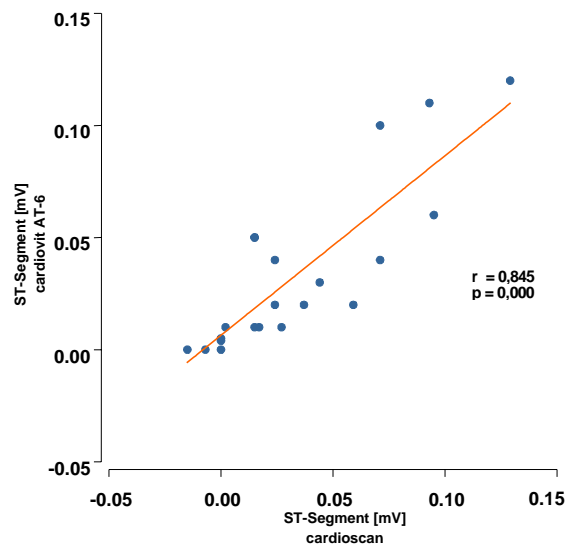


Fig. 7: Correlation between the measured deviations of the ST segments of the cardioscan CS-3 1.0 and the Cardiovit AT-60

Whereby $p \leq 0.05$ is significant, $p \leq 0.01$ is highly significant, $p \leq 0.00$ is most significant

3.3 Correlation between the results of the SF-36 questionnaire and the stress value from the vicardio 1.0.4 and the cardioscan CS-3 1.0

The various items on the SF questionnaire relating to the general state of health showed only a slightly positive and sometimes negative correlation to the stress grade from the vicardio 1.0.4 ($r = -0.175 - 0.138$) (see fig. 8).

The same results were also found for the cardioscan CS-3 1.0. Here the correlation coefficient between the various items of the SF questionnaire and the stress grade lay between $r = -0.253$ and $r = 0.260$ (see fig. 9).

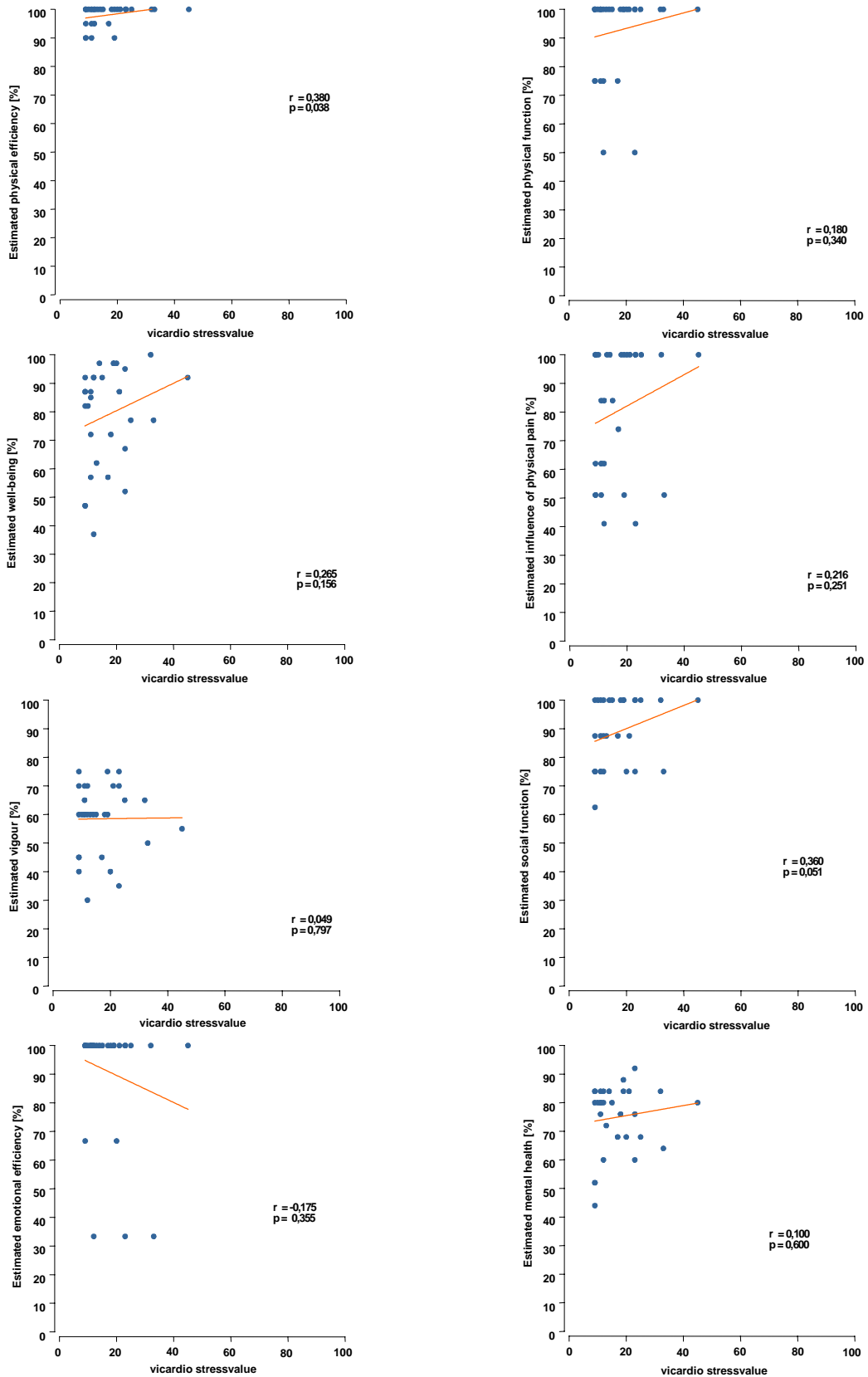


Fig. 8: Correlation between the items of the SF-36 questionnaire and the stress grade from the vicardio 1.0.4

Whereby $p \leq 0.05$ is significant, $p \leq 0.01$ is highly significant, $p \leq 0.00$ is most significant

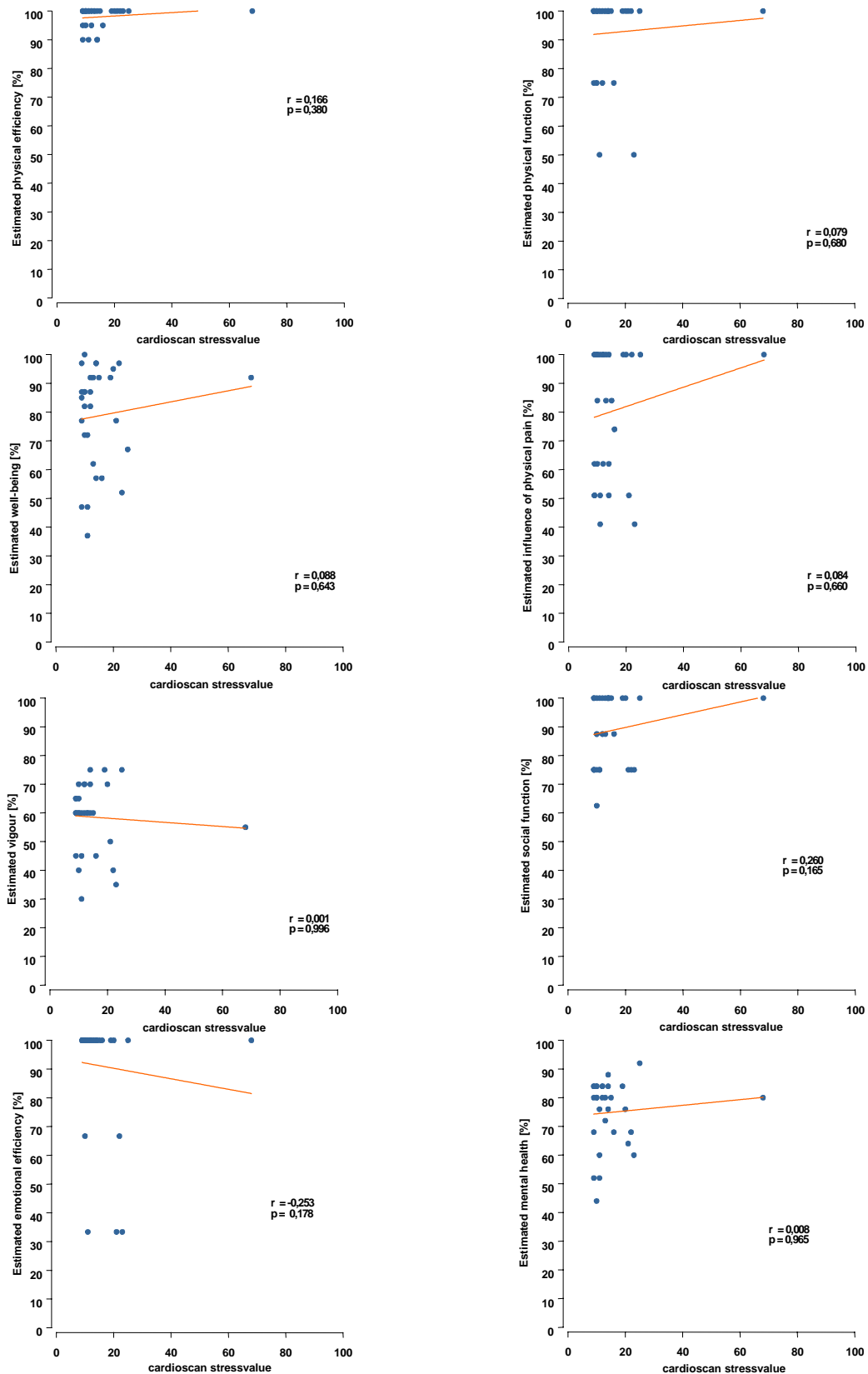


Fig. 9: Correlation between the items on the SF-36 questionnaire and the stress grade from the cardioscan CS-3 1.0

Whereby $p \leq 0.05$ is significant, $p \leq 0.01$ is highly significant, $p \leq 0.00$ is most significant

4 Conclusions

Throughout the trial there was a very good concordance between the data extracted from the ECG by the vicardio 1.0.4 and the cardioscan CS-3 1.0 and those from the standard ECG device. Thus, the detected differences and their standard deviations for PQ interval, QRS duration and QT interval were well below the deviation limits of the current DIN norm for biological measurements using an ECG (DIN EN 60601-2-51).

Table 4: Current DIN norm (DIN EN 60601-2-51) and the measured differences and standard deviations for the vicardio 1.0.4 and cardioscan CS-3 1.0

	DIN norm	vicardio 1.0.4	cardioscan CS-3 1.0
PQ interval	+/- 10 ± 10ms	-4.45 ± 8.26	-3.30 ± 10.92
QRS duration	+/- 10 ± 10ms	-1.07 ± 6.15	4.28 ± 9.21
QT interval	+/- 25 ± 30ms	-2.38 ± 28.01	-18.05 ± 21.37

The deviations that are, however, present may be explained by the non-simultaneous measurements (see Chapter 2.3.2 Validity trial and blood pressure measurement) of the ECG signals using the various devices and ultimately reflect the physiological variability of heart activity. A simultaneous measurement of the signals would, admittedly, allow a direct comparison of the data but was not possible due to the mutual electrical interference of the derivations (see Chapter 2.3.2).

Also, slight deviations due to electrical derivation interference within the individual measurement could have arisen. This is all the more likely as all three devices calculate the ECG data from unfiltered data.

The correlation calculations showed a high correlation between the acquired data from the Cardiovit AT-60 and the vicardio 1.0.4. However, the QT interval showed only a medium correlation between the Cardiovit AT-60 and the cardioscan CS-3 1.0.

What must be taken into account here is that a correlation indicates the extent to which two values tend towards the same direction.

As the correlation diagrams show, the values from the vicardio 1.0.4 and the cardioscan CS-3 1.0 - in comparison to the values from the Cardiovit AT-60 – tend both upwards and downwards. There are just as many deviations in the positive as the negative direction, which could explain the anomalous correlation coefficients. On the other hand, in particular with the QT interval, two noticeable outliers in the lower part of the diagram can be seen which have a corresponding influence on the correlation coefficients – which is noticeably visible on the regression level represented here.

A reliable indicator of an ST segment elevation or depression could be shown for both the vicardio 1.0.4 and the cardioscan CS-3 1.0.

A correlation between the results of the SF-36 questionnaire and the stress value from the vicardio 1.0.4 and the cardioscan CS-3 1.0 could not be found. For this, there are the following interpretations:

To begin with it could be concluded that the questionnaire chosen was not suitable for a comparative investigation of the stress grade. This is quite possible as the data in the questionnaire consisted of a subjective estimation of the state of health and the vicardio 1.0.4 and cardioscan CS-3 1.0 solely take into account physiological parameters,.

Additionally, it is also known that a good or poor physiological state may not necessarily always be perceived individually. A self-assessment of one's own state of health seems, therefore, due to the subjective measurement process, not to be sufficient and should be corrected and supported by objective measurement and screening systems. For early detection of a possible limitation of the cardiovascular system and following corresponding intervention, a regular physiological check of the ECG (including the HRV) using a vicardio 1.0.4 or cardioscan CS-3 1.0 is recommended. Along with an objective assessment, it is also possible to train and adjust the subjective feeling of health.

For the future, it still remains to be tested as to how the condition grade and stress value correlate with the standard examination methods (echocardiography, expert appraisal of a resting and stress ECG, carotid ultrasound diagnosis, endothelial dysfunctions etc.).

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