Sensor validation in medical technology

The comparison of two ECG measurement devices using statistical methods

Graduate

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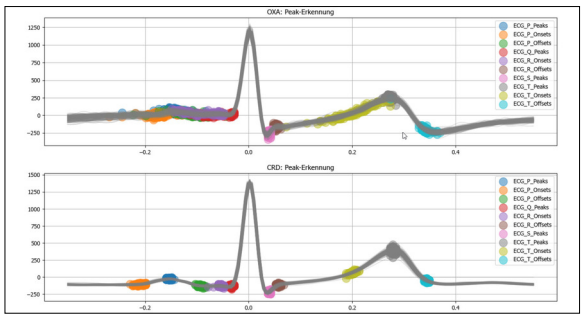
Initial Situation: An ECG monitor is used to measure and monitor the electrical activity of the heart. There are various measuring systems on the market for this purpose. The devices are used either in the consumer sector or for clinical purposes. A product called Oxa, which is approved for the consumer sector, was developed by the spin-off company Nanoleq. This measuring system consists of a garment, an app and a sensor. These components work together to measure heart activity and respiration. In contrast to smartwatches, the Oxa's measuring principle is based on electrical rather than optical measurements. As a result, Oxa is characterized by a higher precision. Nevertheless, Oxa is currently only approved for consumer use and is to be tested for its suitability for medical use. The CardioScreen 2000 device, which is approved for cardiovascular diagnoses, was used as the reference product. As can be seen in Fig. 1, Oxa consists of two dry electrodes which record the ECG under the chest using a monopolar lead configuration. CardioScreen 2000 uses three gel electrodes in a Einthoven configuration. The aim of this thesis is to investigate the suitability of Oxa for medical use. Therefore, the question of how precise the ECG data of the Oxa system is compared to the reference device CardioScreen 2000 was investigated.

Approach / Technology: The data for this validation was obtained by simultaneous measurement of both systems on 20 test subjects. The measurements were taken during different measurement phases, e.g. in resting phases or during or during physical activity. The analysis was done with the help of various Python libraries. The Neurokit2 library was used specifically for ECG feature recognition. This helped to recognize the characteristic points in the ECG signal. Fig. 2 shows the cardiac cycles with the recognized points which are superimposed to provide an overview. These intervals were determined and compared by both measuring systems. In addition, the heart rate variability was also analyzed. The purpose of the evaluation is to check the agreement between the measuring devices and to determine whether the accuracy of the Oxa system is sufficient for a clinical application. The BlandAltman analysis proved to be best suited for this purpose. The Bland-Altman diagrams (Fig. 3) show the difference above the mean value of the two measuring systems. To evaluate the quality, the standard deviations of the difference and the deviation of the mean value (bias) are determined and discussed in a medical context.

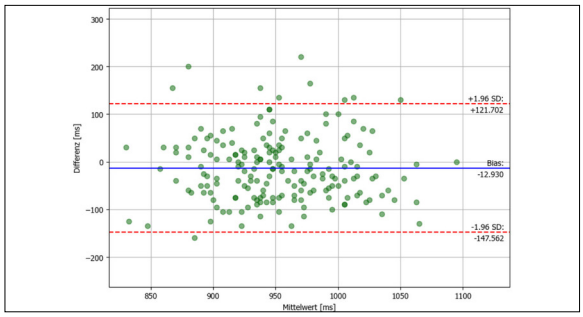
Result: Based on the results, it was found that Oxa showed good agreement with the CardioScreen 2000 in the HRV analysis. In the resting phase, Oxa showed a deviation of less than 2 milliseconds in the mean value of the RR duration. However, for intervals within a cardiac cycle, such as QRS, PQ and QT duration, both meters were imprecise. The measuring devices recorded interval times above the standard limits, which serve as threshold values for cardiac dysfunction. Although the test subjects were healthy, both devices displayed approx. 38% of the intervals above the standard limits. This indicates that the precision of both measuring devices might not be sufficient for clinical purpouses.

[1] Measuring device: CardioScreen 2000 and Oxa
https://www.medis.company/de/ and https://ch.oxalife.com/

[2] Recognized ECG features of a test subject with Oxa (top) and CardioScreen 2000 (bottom)
Own presentment



[3] Bland-Altman plot created for the evaluation of a test subject
Own presentment



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Subject Area
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