The validated and evaluated measurement of heart rate variability (HRV)

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Analysis of the Autonomic Nervous System

White Paper

Scientific Quality Assurance of the ANS Analysis

Evidence Based Evaluation of the Autonomic Nervous System Based on Short-Term Heart Rate Variability

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ANS Analysis
Scientific Quality Assurance and Standards

The entire team of COMMIT GmbH, from our employees, to our sales representatives and scientific consultants, strive to fulfill the utmost in quality standards and industry expectations. It is only by adhering to the highest scientific criteria and demands, what we feel is an indispensible prerequisite in the medical field, that we can ensure the continued quality of the ANS Analysis for users and potential customers.

In recent years, therapeutic analysis of the autonomic nervous system has risen exponentially in the medical community. To maintain appropriate use as an evidence based, analytical and therapeutic tool, the quality standards of data assessment, analysis, interpretation, and classification of reference values are essential.

For quality assurance of the product and to ensure the highest confidence value for the practitioner, we have published the current status of HRV-research in the following White Paper, in cooperation with our scientific consultants for heart rate variability (HRV) and the autonomic nervous system (ANS). Thereby, we would like to demonstrate our guarantee that ANS Analysis fulfills the highest possible scientific standards and requirements.

Clinical and Therapeutical Relevance

The evaluation of the autonomic nervous system (ANS) by means of (short-term) heart rate variability (HRV) represents an established clinical and analytical tool with a long history (Billman, 2011) currently having more than 1,000 related publications per year (Sassi et al., 2015). HRV assesses beat-to-beat variability of consecutive R-waves derived from ECG-measurements within a given period of time. For more than 20 years, HRV-analysis is considered an evidence based quantitative noninvasive means of assessing cardiovascular autonomic functioning (Task Force, 1996; Berntson, 1997). Established and well-defined HRV-indices draw a valid and reliable picture of ANS-functioning and enable a detailed evaluation of the impact of therapeutic treatments. Thus, distinct markers of HRV provide an important analytical tool for all medical and therapeutical fields, where an evaluation of cardiovascular autonomic functioning seems to be relevant (Kleiger et al., 2005). Most of all, HRV-analysis provides an excellent screening-tool for cardiovascular risk stratification in different clinical and therapeutic settings and populations (Thayer et al., 2007, 2010).

Methodological Background

Data Assessment and Data Analysis

The ANS Analysis assesses short-term HRV via high-resolution bi-polar chest belt detection, showing high consistency with high-resolution ECG-measurement systems in a wide range of settings and populations (e.g. Loimaala et al., 1999; Chellakumar et al., 2005; Nunan et al., 2008, 2009; Weippert et al., 2010). The bi-polar chest belt detection site used in ANS Analysis provides an RR-detection with an accuracy of ± 1ms (Ruha et al., 1997) and satisfies guidelines for valid HRV analysis even in cases of small RR-fluctuations (Task Force, 1996; Berntson et al., 1997).
ANS Analysis calculates established and relevant HRV-indices: mean heart rate (HR), the standard deviation of all normal-to-normal RR-intervals (SDNN, measure of overall variability), the square root of the mean of the sum of the squares of differences between adjacent RR-intervals (RMSSD, measure of parasympathetic activity), the stress index as an index of the relation between height and width of RR-distribution (SI, measure of sympathetic activity) and alpha1 of detrended fluctuation analysis (measure of self-similarity and fractal organisation of ANS). These measures characterise the most important aspects of autonomic functioning in both short and long term assessments and are of prognostic relevance for different populations (e.g. Pentilla et al., 2001; Kleiger et al., 2005; Perkiomäki et al., 2005; et al.; Banzer et al., 2006, Al Haddad et al., 2011; Saboul et al., 2013; Buchheit, 2014).

With the ANS Analysis, software quality management is ensured by comparing the systems HRV indices (incl. artefact correction) with a scientific reference software (Kubios HRV 2.1, Tarvainen et al., 2014) on a regular basis. An analysis of more than 150 patients of both sexes with a wide range of clinical indications (age: 20-80 years, heart rate: 40-120 bpm) shows negligible mean differences of the main indices HR, SDNN, RMSSD and alpha1 (<0,4%) as well as a strong relation between SI and the triangular index (r2=0,75) from the reference software.

Reference Values

Normal reference values in ANS Analysis are based on a systematic review and meta-analysis of short-term HRV measures in more than 20,000 healthy adults (Nunan et al., 2010). Additionally, several methodological factors contributing to large variations in HRV values and distributions are incorporated (Pikkujamsa et al., 2001; Kleiger et al., 2005; Sandercock et al., 2005; Sandercock, 2007, Buchheit, 2014). Furthermore, potential changes with age (Antelmi et al, 2004; De Meersman & Stein, 2007) as well as clinically relevant cut-off-values for risk stratification for different populations and adjustments for lifestyle factors and/or physical activity/fitness levels are considered (Kuperi et al., 1993; Liao et al., 1996, 2002; Aubert et al., 2003; Rennie et al., 2003; Schroeder et al, 2003, Buchheit et al., 2005; Thayer et al., 2007, 2010; Sandercock et al., 2008; Pivatelli et al., 2012). Therefore, the normal reference values in the ANS Analysis are applicable to a wide range of settings and subject populations.

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