BEYOND FITBIT: A CRITICAL APPRAISAL OF OPTICAL HEART RATE MONITORING WEARABLES AND APPS, THEIR CURRENT LIMITATIONS AND LEGAL IMPLICATIONS

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ABSTRACT

Fitness and health-care-oriented wearables and apps have been around for a couple of years and are still gaining momentum. Over time, they have begun to harness considerable computational power and to incorporate increasingly sophisticated sensors, eventually resulting in a blurring of the lines between consumer electronics and medical devices. While their benefits and potentials are undisputed, the overly optimistic appraisal commonly encountered in both mass media and academic literature does not adequately reflect unsolved problems and inherent limitations of these devices. This Article will argue that while these issues have long been known to the engineering community, their relevance and legal implications appear to have been grossly underestimated. January 2016 marked a turning point, as news of two class-action lawsuits filed against major manufacturer *Fitbit* brought widespread attention to accuracy, reliability, and safety concerns regarding these devices. This Article will provide a concise overview of optical heart rate monitoring technology, the current state of the art, and research trends. It will be argued that under real-world scenarios these apps and devices are currently inherently inaccurate and unreliable, with even greater problems on the horizon as the

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industry shifts towards areas such as heart rate variability monitoring or the detection of cardiac arrhythmias.

INTRODUCTION

Fitness-oriented wearables of the first generation relied merely on pedometric activity tracking and were able to provide estimates of daily step count and gross approximations of caloric expenditure.[2] More recent devices offer additional functionality, most importantly optical heart rate (HR)[3] monitoring through photoplethysmographic (PPG) measurements.[4] Early adopters gave rise to a "quantified self" movement fascinated by the continuous monitoring of physiological parameters for the purpose of self-optimization and empowerment.[5] Concerns regarding the "Internet of Things" (IoT) in general and smart devices for the monitoring of physiological parameters in particular have mainly been raised regarding IT-security aspects[6] and data privacy issues.[7] Without affecting the legitimacy of said concerns, questions regarding advertising claims and eventually the accuracy, reliability, and safety of HR monitoring apps and wearables have only recently gained widespread attention in January 2016, when major player *Fitbit Inc.* was hit with two class-action lawsuits, alleging fraud[8] and the violation of federal securities laws.[9]

Most of the work published so far, however, tends to be unilateral in nature, focusing solely on specific subproblems and lacks in either technical, biomedical, or jurisprudential details and insight. This Article takes a different approach and examines

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[2] Robin Raskin, *'Glorified Pedometers': 5 Facts About Fitbit, Jawbone Up, and Other Wearables*, EVERYDAY HEALTH (last updated Aug. 12, 2014), http://www.everydayhealth.com/columns/tech-pulse/glorified-pedometers-facts-about-fitbit-jawbone-up-other-wearables/.

[3] Valentina Palladino, *How Wearable Heart-Rate Monitors Work, and Which is Best for You*, ARS TECHNICA (Mar. 2, 2017), https://arstechnica.com/gadget s/2017/04/how-wearable-heart-rate-monitors-work-and-which-is-best-for-you/.

[4] *Id.*

[5] *See generally* LIFELOGGING (Stefan Selke ed., Springer VS 1st ed. 2016) (for discussion of one's quantified self).

[6] *See, e.g.*, SRIDIPTA MISRA ET AL., SECURITY CHALLENGES AND APPROACHES IN INTERNET OF THINGS (Springer International Pub., 1st ed. 2017) (elaborating on approaches to tackle the specific security challenges encountered in IoT).

[7] Adam Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns without Derailing Innovation*, 21(2) RICH. J. L. & TECH. 1, 42–43 (2015); *see also* Antigone Peyton, *A Litigator's Guide to the Internet of Things*, 22(3) RICH. J.L. & TECH. 1, 7–8 (2016) (for discussion of privacy issues).

[8] Class Action Complaint, McLellan v. Fitbit, Inc. (N.D. Cal. 2016) (No. 16-cv-36), 2016 WL 64721, at *1–2.

[9] Robb v. Fitbit, Inc., 216 F.Supp.3d 1017, 1017 (N.D. Cal. 2016).

major problem areas irrespective of conventional disciplinary boundaries and explores their interrelationship.

This Article proceeds in three parts: Part I summarizes basic technical principles and the state of the art of optical HR monitoring technology and argues that under actual, real-world scenarios HR monitoring wearables and apps are at present inherently inaccurate and unreliable; Part II scrutinizes prevalent (over)simplified physiological modeling assumptions and shows how parts of academia and industry fail to deliver on exaggerated claims; and Part III considers current legislative frameworks and trends and examines some of the legal implications and open challenges.

I.   BASIC PRINCIPLES, LIMITATIONS AND OPEN CHALLENGES OF OPTICAL HEART RATE MONITORING

Optical sensor technology for the monitoring of physiological processes constitutes a key feature of the current generation of wearables and is likely to maintain its relevance.[10] This is largely based on its cost-effectiveness, relative simplicity, moderate power consumption, and the circumstance that useful and clinically relevant physiological parameters, most importantly arterial oxygen saturation and pulse rate can be obtained from PPG measurements.[11]

A. Basic Principles and Origins of Photoplethysmography

The contemporary popularity of photoplethysmography ("PPG") can be attributed to technological advances in the last few decades, most notably the remarkable advances in the field of light emitting diodes (LED) and the accompanying cost reduction of PPG sensors.[12]

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[10]   David Nield, *How it works: We Explain How Your Fitness Tracker Measures Your Daily Steps,* WEARABLE (June 26, 2017), https://www.wareable.com/fitness-trackers/how-your-fitness-tracker-works-1449.

[11]   *See generally* John Allen, *Photoplethysmography and its Application in Clinical Physiological Measurement*, 28 PHYSIOL MEAS R1, R2 (2007) (discussing the wide array of clinical applications of photoplethysmography); *see also Design of Pulse Oximeters* (John G. Webster ed., CRC Press 1st ed. 1997) (discussing the use of Mphotoplethysmography to estimate arterial oxygen saturation).

[12]   Radovan Stojanovic & Dejan Karadaglic, *An Optical Sensing Approach Based on Light Emitting Diodes*, 76 J. PHYS. CONF. SER 1, 1 (2007).

1. Some Historical Notes

A basic idea of what photoplethysmography ("PPG") is and how it works can be obtained by starting with the dissection of the term itself, more specifically by dissecting it into three components, i.e. "photo-plethysmo-graph."[13] All three can be traced back to Greek roots, specifically "photo" to photos, meaning "light"; "plethysmo" to the Greek "plethusmos," meaning "increase"; and "graph" to "graphe," meaning "writing."[14] Thus, photoplethysmography, as used in this context, refers to the measurement of volumetric changes of blood perfusion during cardiac cycles by optical means.[15] While being closely related and unfortunately often incorrectly used synonymously with pulse oximetry, they are not the same.[16] Pulse oximeters make use of photoplethysmography and can therefore also be used as PPG devices for pulse rate monitoring.[17] On the other hand, a PPG is not necessarily able to perform pulse oximetry (i.e. to estimate arterial oxygen saturation through peripheral oxygen saturation).[18]

Although thought to be a recent invention, PPG dates back to the 1930's,[19] but Japanese electrical engineer Takuo Aoyagi[20] is credited with the invention of modern pulse oximetry in 1972, which he made public two years later.[21] However, it took the aforementioned advances in technology and the resulting availability of more appropriate and suitable light sources (LEDs in particular) to enable practical real-world applications, most notably pulse oximetry, which was commercially introduced in the 1980's[22] and revolutionized the world of modern medicine, in

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[13] John B. West, *The Birth of Clinical Body Plethysmography: It was a Good Week*, 114(8) J CLIN INVEST. 1043, 1043 (2004).

[14] *Id.*

[15] Belle, *How do Fitness Trackers Measure Your Heart Rate?* EXIST (Feb. 21, 2016), https://exist.io/blog/fitness-trackers-heart-rate/.

[16] *See* Justin P. Phillips et al., *Pulse Oximetry and Photoplethysmographic Wave Form Analysis of the Esophagus and Bowel*, 21 CURR OPIN ANAESTHESIOL 779, 779 (2007) (discussing common misunderstandings with pulse oximetry).

[17] AYMEN A. ALIAN & KIRK H. SHELLEY, MONITORING TECHNOLOGIES IN ACUTE CARE ENVIRONMENTS 165 (J. M. Ehrenfield & M. Cannesson eds., Springer 2014).

[18] Meir Nitzan et al., *Calibration-Free Pulse Oximetry Based on Two Wavelengths in the Infrared — A Preliminary Study*, 14 SENSORS 7420, 7421 (2014).

[19] John W. Severinghaus, *Takuo Aoyagi: Discovery of Pulse Oximetry,* 105(6) ANEST. ANALG. S1, S2 (2007) (discussing the historical roots of pulse oximetry).

[20] *See* Takuo Aoyagi, *Pulse oximetry: its Invention, Theory, and Future*, 259 J ANESTH. 259, 260 (2003) (discussing the origins of pulse oximetry).

[21] Severinghaus, *supra* note 19, at S2.

[22] *See* Allen, *supra* note 11, at R4 (discussing photoplethysmography in recent

particular the field of anesthesiology where it became a standard equipment by the mid-to-late 1980's.[23] Yet, the widespread use of pulse oximetry does not necessarily go along with an adequate appreciation of its mechanism of action and the resulting limitations.[24]

2.   Basic Principles of Photoplethysmography

A PPG device consists of at least one light source illuminating an area of blood-perfused tissue and at least one nearby photodetector.[25] The intensity of the light captured by the detector is subject to continuous variations caused by a multitude of light-tissue interactions, such as absorption, transmission, reflection, and scattering.[26]

The relative placement of source and detector gives rise to two distinct PPG configurations or modes of operation, namely "transmission mode," where source and detector are placed on opposite sides of the blood-perfused tissue, and "reflectance mode," where the detector is placed adjacent to the light source.[27] The two modes are distinctive in that the predominant pathway by which the injected photons reach the detector differ.[28] If LED and photodetector are on opposite sides of the tissue, as is the case in finger- or ear-clip devices, the signal at the detector predominantly arises from the transmittive pathway, whereas in a reflective PPG device, the backscattering of light is predominant.[29]

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decades).

[23]   *Id.* at R11.

[24]   *See, e.g.,* Edward D. Chan et al., *Pulse Oximetry: Understanding its Basic Principles Facilitates Appreciation of its Limitations*, 107(6) RESPIR MED 789, 790 (2013) (discussing the common lack of understanding among health professionals of basic functioning principles of pulse oximetry).

[25]   *See* Mohamed Elgendi, *On the Analysis of Fingertip Photoplethysmogram Signals*, 8 CURR CARDIOL REV. 14, 17 (2012) (discussing how a photoplethysmogram functions).

[26]   *See generally* Paul D. Mannheimer, *The Light-Tissue Interaction of Pulse Oximetry*, 105(6) ANESTH & ANALG S10, S10–S17 (2007) (discussing in depth the involved optical phenomena).

[27]   Toshiyo Tamura et al., *Wearable Photoplethysmographic Sensors—Past and Present*, 3 ELECTRON. 282, 284–85 (2014).

[28]   *Id.* at 284.

[29]   *See* Lucas V. Besteiro et al., *Simple and Complex Metafluids and Metastructures with Sharp Spectral Features ina Broad Extinction Spectrum:Particle–Particle Ineractions and Testing the Limits of the Beer-Lambert Law*, 121 J. PHYS. CHEM. C 2987, 2992 (2017) (discussing the Beer-Lambert Law). It is important to stress that the commonly used terminology (i.e., transmission and reflection mode) and the conventional mathematical formulation of pulse oximetry by means of the Beer-Lambert law represent simplifications to yield a qualitative

The attenuation of light from the emitting source to the detector is commonly expressed as being subject to an exponential decay, according to Beer-Lambert's law, and depicted by the following equation.[30]

$$I = I_0 e^{-\epsilon(\lambda)Cl}$$

In this equation, I_0 represents the incident light intensity, ϵ the absorption (or extinction) coefficient for a particular substance, which is a function of the light's wavelength λ, C the concentration of said substance and l the length of the path traveled by the light.[31]

To illustrate the basic concept of how a PPG device (or, for that matter, any modern smartphone equipped with a camera and an LED flash) obtains its characteristic pulsatile signal from which PR can be inferred, think of all the terms in the above equation to be constant, except the path lengths traveled by the emitted light, which remain relatively constant for veins, capillaries and other "stationary body tissues" (contributing to the "DC-component" of the PPG signal). These exhibit a cyclic fluctuation Δl (contributing to the "AC-component" of the PPG signal) regarding the arterial blood components as the arteries slightly dilate during systole, thereby causing a small increase in path lengths, and relax again during diastole, demonstrated by the following equation.[32]

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understanding rather than a formally correct representation.

[30] *See generally, e.g.*, Mannheimer, *supra* note 26; *see also* Michael S. Patterson et al., *Time Resolved Reflectance and Transmittance for the Non-invasive Measurement of Tissue Optical Properties*, 28(12) APPL. OPT 2331, 2331 (1989) (discussing scattering coefficients and mediums); *see also* Joseph M. Schmitt, *Simple Photon Diffusion Analysis of the Effects of Multiple Scattering on Pulse Oximetry*, 38(12) IEEE TRANS. BIOMED. ENG. 1194, 1194 (1991) (discussing how Beer-Lambert Law accounts for scattering of light in tissue and other inaccuracies); *see generally* Wesley B. Baker et al., *Modified Beer-Lambert law for Blood Flow*, 5(11) BIOMED. OPT. EXPRESS 4053 (2014). While the mathematical expression in terms of Beer-Lambert's law represents a commonly used simplification to convey a qualitative understanding of the physical principles underlying pulse oximetry, it has to be stressed that Beer-Lambert's law does not take into account scattering effects. In pulse oximetry, scattering is significant (thereby allowing "reflective pulse oximetry" to work) and cannot be neglected. In fact, the overall light attenuation is affected by both absorption and scattering effects in a rather intricate way. A more appropriate representation is given by the modified Beer-Lambert law, wherein mean photon path lengths are used to account for the increased actual path lengths due to tissue scattering. However, for the scope of this article, the simplistic formulation in terms of the conventional Beer-Lambert law shall suffice.

[31] *See* Schmitt, *supra* note 30, at 1199.

[32] LISA MARCUCCI, AVOIDING COMMON ICU ERRORS 234 (Brian Brown et al.

$$\Delta I \approx I_0 e^{-\epsilon(\lambda)C\underbrace{(l_{DIA}+l_{SYS})}_{\Delta l}}$$

This cyclic fluctuation yields the characteristic waveform depicted in Figure 1 (bottom line), with Figure 1 (top line) showing the respective synchronized electrocardiography (ECG) recording simply for the sake of comparison.[33] ECG monitors the electrical activity of the heart by recording electrical potentials through electrodes placed at the surface of the skin.[34] ECG represents the "gold-standard" for cardiac monitoring.[35] Note the sharper, more pronounced peaks in the ECG signal compared to the PPG signal.
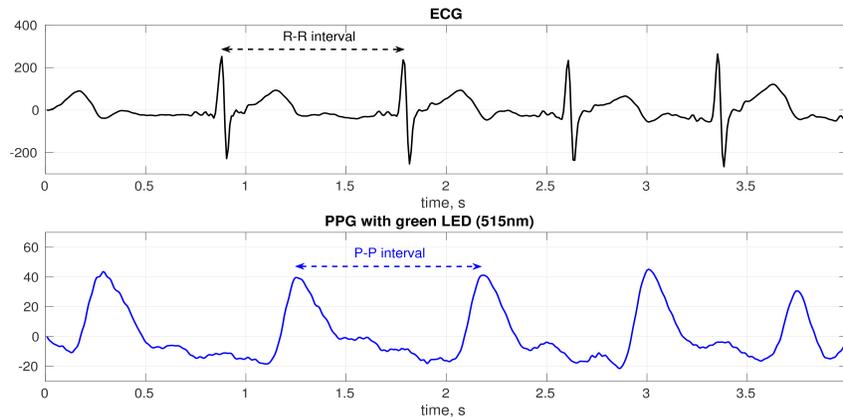
Figure 1: Excerpt of typical synchronized ECG and PPG recording

eds., 2007).

[33] *See* Zhilin Zhang et al., *TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise*, 62(2) IEEE TRANS. ON BIOMED. ENG. 522, 529 (2015) (showing the first 4 seconds of a synchronized ECG and PPG recording from the dataset by Zhang et al. (Subject 8)).

[34] Diane R. Karlus, *ECG Primer: The Leads of a 12-lead ECG,* KANSAS CITY U. OF MED. AND BIOSCIENCES, https://courses.kcumb.edu/physio/ecg%20primer /ecgleads.htm.

[35] *See* PIERO C. FRANZONE ET AL., MATHEMATICAL CARDIAC ELECTROPHYSIOLO GY 15 (Springer 2014) (discussing ECG range of diagnosis); *see also* Ufuk Bal, *Non-contact Estimation of Heart Rate and Oxygen Saturation Using Ambient Light,* 6 BIOMED. OPT. EXPRESS 86, 87 (2015) (naming EEG as the gold standard).

B. Optical Heart Rate Monitoring through Photoplethysmography

Basic pulse oximetry requires at least two light sources of different and carefully selected peak wavelengths to determine the concentration of specific constituents of the blood, namely oxygenated hemoglobin (O_2HB), also called oxyhemoglobin, and deoxygenated hemoglobin (HHb) to determine peripheral oxygen saturation (SpO_2), which serves as an estimate of arterial oxygen saturation (SaO_2).[36]

These requirements relax when one only aims at the extraction of HR estimates.[37] For, under ideal conditions, the use of a single LED is sufficient to yield a characteristic pulsatile PPG waveform.[38] Therefore, assuming an accurate and reliable PPG pulse peak detection, both pulse rate ("PR") and pulse rate variability ("PRV") can be obtained.[39]

It is, however, equally evident that accurately detecting PPG pulse peaks may be somewhat more challenging than the detection of R-peaks in an ECG signal, for the latter are more pronounced.[40] Furthermore, the ECG and PPG signals depicted in Figure 1 are "ideal" in that they are virtually not corrupted by noise or motion artifacts, which is not necessarily consistent with real-life acquisition scenarios for such signals.[41]

Numerous methods for the real-time detection of the QRS complex[42] in an ECG have been proposed and improved on over the

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[36] *See, e.g.*, Chan et al., *supra* note 24, at 790; *see also* Webster, *supra* note 11; ELAINE M. KEOHANE ET AL., RODAK'S HEMATOLOGY: CLINICAL PRINCIPLES AND APPLICATIONS 131 (5th ed. 2015) (discussing the foundation of pulse oximetry).

[37] *See* Bal, *supra* note 35, at 97 (discussing heart rate results compared to blood saturation results).

[38] Robert Amelard et al., *Spatial Probabilistic Pulsality Model for Enhancing Photoplethysmographic Imaging Systems*, 21(11) J. BIOMED. OPT 1, 1 (2016)

[39] *Id.*

[40] *See Comparison Chart: Electrical (ECG) vs. Optical-based (PPG): Biosensors in Wearable Devices*, NEUROSKY, http://neurosky.com/resource/ecg-vs-ppg-chart/ (explaining that EEG signals can be extracted with millisecond level accuracy, whereas PPG's are more limited).

[41] Po-Hsiang Lai & Insoo Kim, *Lightweight Wrist Photoplethysmography for Heavy Exercise: Motion Robust Heart Rate Monitoring Algorithm*, 2 HEALTHC. TECHNOL. LETT. 6, 6 (2015) (explaining that PPG sensors are susceptible to motion artifacts).

[42] QRS complex refers to the name for the combination of three of the graphical deflections seen on a typical electrocardiogram.

last couple of decades.[43] These computationally efficient algorithms are usually first-derivative-based and the method by Pan and Tompkins[44] has established itself as the reference in the field.[45] As for PPG, no actual "gold-standard" has necessarily been established yet, but several approaches have been proposed, usually involving the detection of maxima, minima, zero-crossings, or other signal characteristics.[46]

The (instantaneous) heart rate ("HR") is usually calculated from the time difference between successive R-peaks in the ECG time series and expressed in beats per minute ("BPM"), demonstrated by the following equation,

$$HR = \frac{1}{t_{R-R}} * 60$$

where t_{R-R} is the time difference between two R-peaks expressed in seconds, as depicted in Figure 1 (top line).[47]

The (instantaneous) PR is obtained accordingly through the respective time difference between two pulse peaks, demonstrated by the following equation,

$$PR = \frac{1}{t_{P-P}} * 60$$

where t_{P-P} is the time difference between the two P-P peaks expressed in seconds, as depicted in Figure 1 (bottom line).[48]

The time-series of R-R intervals (also referred to as "tachogram") are often scrutinized in time and/or frequency domain in the course of Heart Rate Variability ("HRV") analysis to assess aspects pertaining to the functioning of the autonomic nervous system,

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[43] Hamed Beyramienanlou & Nasser Lotfivand, *Shannon's Energy Based Algorithm in ECG Signal Processing,* 2017 COMPUT MATH METHODS IN MED. 1, 1 (2017) (discussing various methods to detect heart signal waves).

[44] *See* Jiapu Pan and Willis J. Tompkins, *A Real-Time QRS Detection Algorithm*, BME-32(3) IEEE TRANS BIOMED ENG 230, 230 (1985) (introducing the real-time QRS detector by Pan and Tompkins).

[45] *See, e.g.*, Natalia M. Arzeno et al., *Analysis of First-Derivative Based QRS Detection Algorithms*, 55(2) IEEE TRANS. BIOMED ENG. 478, 478–79 (2008) (discussing various first-derivative-based QRS detectors).

[46] *See, e.g.*, Mateo Aboy et al., *An Automatic Beat Detection Algorithm for Pressure Signals*, 52(10) IEEE TRANS BIOMED ENG. 1662, 1665 (2005) (introducing one such proposal).

[47] *See supra* Part I, Section A for Figure 1.

[48] *Id.*

more specifically the sympathetic and parasympathetic subsystems.[49] The same holds for the series of P-P intervals derived from a PPG signal, as PRV is increasingly used as HRV surrogate.[50]

C.   The Problem of Motion Artifacts

In real application scenarios, both ECG and PPG are severely affected by numerous interferences, most notably motion-induced artifacts.[51] The challenge of artifact removal however is not limited to ECG/PPG but is rather an issue encountered in the acquisition and processing of physiological signals in general.[52] It is well established, though, that due to different underlying functioning principles, sensor-skin coupling and sensor positioning PPG is affected by motion-induced artifacts to a greater extent than ECG is.[53]

Focusing on PPG, motion artifacts may arise due to the following phenomena[54]:

- deteriorations in the sensor-skin coupling due to a loosely worn wearable subject to acceleration forces;[55]
- sensor contact force, i.e. the pressure between the optical probe and the skin, where
- insufficient pressure yields inadequate coupling to the skin and therefore low AC amplitude and possibly even loss of contact;[56]

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[49] *See infra* Part II for an explanation of the feedback mechanisms of sympathetic and parasympathetic subsystems.

[50] *See infra* Part II for a discussion of the caveats regarding using PRV as an HR surrogate.

[51] *See* Kevin T. Sweeney et al., *Artifact Removal in Physiological Signals–Practices and Possibilites*, 16(3) IEEE TRANS INFO. TECHNOL BIOMED 488, 490 (2012) (discussing the different effects motion has on ECGs and PPGs).

[52] *Id.*

[53] Eduardo Gil et al., *Photoplethysmography Pulse Rate Variability as a Surrogate Measurement of Heart Rate Variability during Non-Stationary Conditions*, 31 PHYSIOL MEAS 1271, 1287 (2010); Axel Schäfer & Jan Vagedes, *How Accurate is Pulse Rate Variability as an Estimate of Heart Rate Variability: A Review on Studies Comparing Photoplethysmographic Technology with an Electrocardiogram*, 166 INT J CARDIOL.15, 18–20, 26–27 (2013).

[54] *See* Mathieu Lemay et al., *Application of Optical Heart Rate Monitoring* 114–15, in WEARABLE SENSORS: FUNDAMENTALS, IMPLEMENTATION AND APPLICATIONS (Edward Sazonov & Michel R. Neuman eds., Academic Press 1st ed. 2014) (for discussion of motion artifacts).

[55] *See* Tamura, *supra* note 27, at 285 (explaining how several factors can affect PPG recordings, such as measurement site).

[56] *Id.*

- excessive pressure may distort the signal and eventually result in signal loss due to the occlusion of blood vessels;[57]
- the impact of acceleration and gravitational forces on bodily tissues which yields to changes in both shape and composition.[58]
- Note that this type of artifacts heavily depends on probe positioning, e.g. ear and forehead are known to be less influenced compared to other peripheral sites such as fingers and wrist.[59]

Thus, mitigating the detrimental effects of motion artifacts can be seen as the greatest signal processing challenge with regards to PPG. Letting $s(n)$ be a PPG signal and $m(n)$ a motion-induced artifacts signal, the need for a model for the actual observed signal, which shall be denoted as $y(n)$, raises the question of how exactly $m(n)$ contributes to $y(n)$.

Throughout the literature, the predominantly used model assumes that the observed signal is merely the additive combination of PPG and motion-induced artifacts,[60] which translates to a simple additive combination in the frequency domain as well, demonstrated by, $y_{add}(n) = s(n) + m(n) \rightarrow Y_{add}(\omega) = S(\omega) + M(\omega)$[61] However, the validity of the simple additive model must be questioned.[62] Lemay argues that "the combination of multiplicative and additive models, possibly with nonlinear relations, is certainly more representative of the real relations that exist between the motion and the motion artifacts observed in the PPG signals."[63] Lemay proposes to describe y (n) as the sum of s (n) and a weighted multiplication of both pulse and motion components, demonstrated by the following, $y_{mul}(n) = [1 + \alpha \cdot m(n)] \cdot s(n) \rightarrow Y_{mul}(\omega) = S(\omega) + \alpha M(\omega) \otimes S(\omega)$

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[57] *Id.*

[58] Amirhosein K. Ahmadi et al., *Heart Rate monitoring during physical exercise using wrist-type photoplethysmographic (PPG) signals, 37TH ANNUAL INT'L CONF. OF THE IEEE* 6166-6169 (2015).

[59] *See* Yuka Meada et al., *Relationship Between Measurement Site and Motion Artifacts in Wearable Reflected Photoplethysmography*, 35 J MED SYST. 969–76 (2011) (discussing in further detail the measurement site's influence on signal quality).

[60] *Id.*

[61] This equation is figuratively depicted in Figure 2.

[62] *See, e.g.*, Peter Gibbs & H. Harry Asada, *Reducing Motion Artifact in Wearable Bio-Sensors Using MEMS Accelerometers for Active Noise Cancellation*, PROC. AM. CONTROL. CONF. 1581, 1582–83 (2005).

[63] Lemay, *supra* note 54, at 115.

Note that since a multiplication in time-domain equals a convolution in frequency domain (and vice versa), this results in a convolution of the spectral components of pulse and motion signals, possibly resulting in a signal with distorted and overlapping frequency components that may no longer be separable by simple filtering means,[64] as depicted in Figure 2 (bottom).
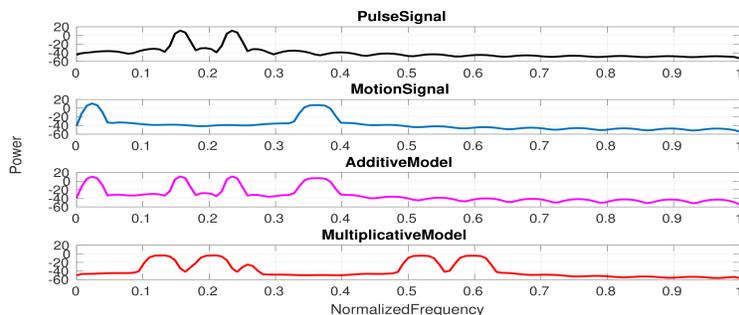

Figure 2: Welch periodograms of the pulse and motion signals (just for illustration purposes, i.e. the signal depicted here are just composed of chirp signals and not actual PPG and accelerometer data), $S(\omega)$ and $M(\omega)$, respectively, and their interaction following either an additive model $Y_{add}(\omega)$ or a multiplicative model $Y_{mul}(\omega)$ (with $\alpha \sim N(0,1)$, i.e. a standard normally distributed multiplication factor).[65]

D. Prior Art and Research Trends

The problem of motion artifact suppression has increasingly been treated in the signal processing literature[66] and is still gaining momentum due to the increasing prevalence of and reliance upon low-cost physiological sensors such as PPG.[67] An

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[64] STEVEN W. SMITH, THE SCIENTIST AND ENGINEER'S GUIDE TO DIGITAL SIGNAL PROCESSING 309 (California Technical Pub. 2011).

[65] See Lemay, *supra* note 54, at 115–16.

[66] *See* M. Malekmohammadi & A. Moein, *A Brief Comparison of Adaptive Noise Cancellation, Wavelet and Cycle-by-Cycle Fourier Series Analysis for Reduction of Motional Artifacts from PPG Signals*, SOUTHERN BIOMEDICAL ENG. CONF. IFMBE PROC. 243, 243 (K.E. Herold, et al. eds., 2010); Kali V.P. Naraharisetti et al., *Comparison of Different Signal Processing Methods for Reducing Artifacts from Photoplethysmograph Signal*, IEEE INT'L CONF. EIT, 1–8 (2011) (for discussion of common issues).

[67] *See* Yong-sheng Yan, *Reduction of Motion Artifact in Pulse Oximetry by Smoothed Pseudo Wigner-Ville Distribution,* 2(3) J NEUROENG REHABIL (2005) (discussing limitations).

inherent advantage of wearables, smartphones, etc. lies in the additional information they concomitantly sense and provide in addition to the PPG signal itself.[68] Most notably, virtually all of said devices are equipped with Micro-Electro-Mechanical Systems ("MEMS") based accelerometers,[69] which are crucial in the suppression or reduction of motion artifacts.[70] A common and intuitive approach is provided by the use of an adaptive filter to estimate (and then subtract) the motion artifacts in the observed signal using the given accelerometer data as reference signal.[71] Such adaptive noise cancellation approaches have been used by various authors to reduce motion artifacts in PPG signals.[72]

Additionally, a multitude of other methods, including but not limited to Kalman filtering,[73] independent component analysis,[74] wavelets,[75] empirical mode decomposition[76] and singular spectrum

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[68] Muhammad Habib ur Rehman et al., *Mining Personal Data Using Smartphones and Wearable Devices: A Survey,* 15 SENS. 4430, 4434 (2015).

[69] *See* Malekmohammadi, *supra* note 67.

[70] *See generally* Philippe Renevey et al., *Wrist-located Pulse Detection using IR Signals, Activity and Nonlinear Artifact Cancellation*, IEEE EMBS CONF. PROC. (2001) (for discussion of the impact of motion on wearables).

[71] *See generally* SIMON HAYKIN, ADAPTIVE FILTER THEORY (5th ed. 2013); PAULO S.R. DINIZ, ADAPTIVE FILTERING: ALGORITHMS AND PRACTICAL IMPLEMENTATION 1–2, 13 (4th ed. 2013); AURELIO UNCINI, FUNDAMENTALS OF ADAPTIVE SIGNAL PROCESSING (1st ed. 2015); LEONARDO R. VEGA & HERNAN REY, A RAPID INTRODUCTION TO ADAPTIVE FILTERING (1st ed. 2013) (for discussion of adaptive filters).

[72] *See, e.g.*, Rasoul Yousefi et al., *A Motion-Tolerant Adaptive Algorithm for Wearable Photoplethysmographic Biosensors*, 18(2) IEEE J BIOMED HEALTH INFORMAT. 670 (2014); M.R. Ram et al., *On the Performance of AS-LMS Based Adaptive Filter for Reduction of Motion Artifacts from PPG Signals*, IEEE INT'L INSTRUM. & MEAS. TECH. CONF. 1–4 (2011); Tim Schäck et al., *A New Method for Heart Rate Monitoring During Physical Exercise Using Photoplethysmographic Signals*, EUSIPCO 2666, 2670 (2015).

[73] *See* S. Seyedtabaii & L. Seyedtabaii, *Kalman Filter Based Adaptive Reduction of Motion Artifact from Photoplethysmographic Signal*, 2 INT'L J. ELECTRICAL, COMPUTER, ENERGETIC, ELECTRONIC AND COMM. ENGINEERING 13, 15 (2008) (describing the use of a Kalman filter to reduce motion artifact in PPG signals).

[74] *See* Byung S. Kim et al., *Motion Artifact Reduction in Photoplethysmography Using Independent Component Analysis*, 53(3) IEEE TRANS. BIOMED. ENG. 566, 566 (2006) (describing the use of independent component analysis to reduce motion artifact in PPG signals).

[75] *See* M. Raghuram et al., *Evaluation of Wavelets for Reduction of Motion Artifacts in Photoplethysmographic Signals*, 10TH INT'L CONF. ISSPA 460, 460 (2010) (describing the use of wavelet transformation to reduce motion artifact in PPG signals).

[76] *See, e.g.*, Xuxue Sun et al., *Robust Heart Beat Detection from Photoplethysmography Interlaced with Motion Artifacts Based on Empirical Mode Decomposition*, IEEE-EMBS INT'L CONF. ON BIOMED. HEALTH INFORM. 775,

analysis[77] have been proposed in the literature. The influence of the LED's peak wavelength pertaining to the propensity of motion-induced artifacts has also been investigated and it was shown that green LEDs are favorable in that respect.[78]

A recent publication by Zhang[79] received considerable attention, for the authors proposed a general framework (termed TROIKA) for pulse rate monitoring during intensive physical exercise using wrist worn PPG devices and made their set of synchronized PPG and ECG measurements (at rest and while physically active with varying degrees of intensity) available for research purposes.[80] The dataset also laid the foundation for the "IEEE Signal Processing Cup of 2015," which culminated in numerous contributions published shortly thereafter.

One should, however, be cautious when interpreting methods alleging improvements that originated under above mentioned circumstances, for the dataset on which the algorithms were evaluated on was limited and known a-priori, thus allowing for solutions tailored specifically for that particular dataset, which may or may not be representative of the problem at large.[81] As Tenko points out, "the reported improvements in performance are usually accompanied with the increased number of free parameters which may be a sign of overfitting given the fixed size of the dataset on which the algorithms are both designed and tested."[82] Thus, the widespread use of and reliance upon the TROIKA dataset in recent optical HR monitoring research efforts must be questioned, especially given the quite modest costs associated with the gathering of PPG data.[83]

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776 (2012) (describing the use of empirical mode decomposition to reduce motion artifact in PPG signals).

[77] *See, e.g.*, S. M. A. Salehizadeh et al., *Photoplethysmograph Signal Reconstruction Based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal*, 42 ANN. BIOMED. ENG. 2251, 2254 (2014) (describing the use of singular spectrum analysis to reduce motion artifact in PPG signals).

[78] Jihyoung Lee et al., *Comparison Between Red, Green and Blue Light Reflection Photoplethysmography for Heart Rate Monitoring During Motion*, IEEE INT'L CONF. ENG. MED. BIOL. SOC. 1724, 1727 (2013).

[79] Zhang et al., *supra* note 33.

[80] *See id.* at 522–523 (revealing the publication of the datasets used).

[81] *See* Andriy Tenko, *Accurate Wearable Heart Rate Monitoring During Physical Exercises Using PPG*, 64 IEEE TRANS. BIOMED. ENG. 2016, 2016–2017 (2017) (explaining the development and use of the datasets).

[82] *Id.* at 2017.

[83] *See* Shyamal Patel et al., *A Review of Wearable Sensors and Systems with Application in Rehabilitation*, 9 J NEUROENG REHABIL 1, 4 (2012) (suggesting the

In conclusion, optical HR monitoring through PPG is currently unable to provide accurate and reliable real-time results except under ideal conditions (such as healthy subjects at rest). The often-advanced claim that widespread use of PPG based apps and devices would be beneficial to the public health-care system is highly questionable. In fact, this Author would argue that the opposite is more likely, specifically, that the widespread use of inaccurate and unreliable devices in the community would eventually increase the burden on health-care systems due to the large number of false alarms requiring further and costly diagnostic clarification.[84]

II. THE DANGERS OF OVERSIMPLIFYING HUMAN PHYSIOLOGY

While a simplified view or model of human physiology and the cardiovascular system may sometimes be appropriate and useful, and therefore not a problem *per se*, it should only be resorted to conditioned on an awareness of its limitations. As such, some of the dangers of over simplification will be discussed below.

A.   Are HR and PR one and the same?

Heart rate ("HR") and pulse rate ("PR") refer to and are in fact two different phenomena.[85] HR refers to the rate at which the heart contracts, triggered by electric impulses.[86] PR refers to sudden changes in blood pressure that result from pressure waves arising from the ventricular ejection of oxygenated blood into the aorta during cardiac cycles and their propagation throughout the systemic circulatory system.[87] In essence, the pulsatile blood pressure component results from interactions between the left ventricular ejection of the heart and the mechanical properties of large arteries, giving rise to a forward pressure wave, and a reflected pressure wave, which originates at various arterial reflection sites.[88] This rhythmic "peak" of peripheral arterial blood

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use of smartphones for data collection).

[84] Ben Freedman, *Screening for Atrial Fibrillation Using a Smartphone: Is There an App for That?*, J. AM. HEART ASSN. 1, 3 (2013) (discussing the tradeoff between sensitivity and specificity).

[85] *See Heart Rate vs. Pulse*, DIFFEN, http://www.diffen.com/difference/Heart _Rate_vs_Pulse (describing the difference between heart rate and pulse rate).

[86] *Id.*

[87] *Id.*

[88] PAOLO SALVI, PULSE WAVES: HOW VASCULAR HEMODYNAMICS AFFECTS BLOOD PRESSURE 10 (Nicoletta Abbondanza trans., Springer-Verlag Italia 2012).

pressure is easily palpable at specific sites, e.g. by placing the index finger over the carotid, brachial or radial artery.[89] Therefore, while PR may be an appropriate surrogate for HR in healthy individuals under normal conditions, one should be aware of the aforementioned differences, as HR and PR may significantly differ when the ejection of blood during systole becomes impaired due to a heart condition or when peripheral blood perfusion is impaired for whatever reason.[90]

B.   The Popularity of Heart Rate Variability ("HRV")

The analysis of HRV has been attracting considerable research attention.[91] In fact, an exponential growth of respective academic publications has been observed.[92] The review paper by Acharya[93] manages to convey a bird's eye view of some promising results. In addition, Thayer[94] provides a review on the alleged relationship between the autonomic nervous system, HRV, and cardiovascular disease risk factors while Schubert[95] makes a case for the importance of HRV analysis in stress research. Furthermore, Valenza[96] considers the role of autonomic nervous system dynamics in the recognition of mood and emotional states and Ishio[97] recently used wearable PPG devices to record HRV (sic!) for the assessment of the well-being of an aging and depopulating community in Japan. The rationale behind the interest in HRV

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[89]   *Id.*

[90]   *Id.*

[91]   *See* Heikki V. Huikuri et al., *Measurement of Heart Rate Variability: A Clinical Tool or a Research Toy?* 34 J. AM. COLL. CARDIOL, 1878, 1879 (1999) (showing the annual number of publications from 1988 through 1999 regarding HRV).

[92]   *Id.*

[93]   *See* U. Rajendra Acharya et al., *Heart Rate Variability: A Review*, 44 MED BIOL ENG COMPUT, 1031, 1031 (2006) (stating in the abstract that the paper discusses the benefits, applications, and popularity of HRV analysis).

[94]   Julian F. Thayer et al., *The Relationship of Autonomic Imbalance, Heart Rate Variability and Cardiovascular Disease Risk Factors*, INT. J. CARDIOL (2009).

[95]   Christian Schubert & Wayne Bardwell, *Effects of Stress on Heart Rate Complexity—A Comparison Between Short-term and Chronic Stress*, 80 BIOL PSYCHOL. 325, 325 (2008).

[96]   *See* GAETANO VALENZA & ENZO PASQUALE SCILINGO, AUTONOMIC NERVOUS SYSTEM DYNAMICS FOR MOOD AND EMOTIONAL-STATE RECOGNITION 3 (Springer Int'l Pub. 2014) (suggesting that "[t]he automatic *emotion recognition* is one of the most important applications in neuroscience . . . ").

[97]   Junichirou Ishio & Naoya Abe, *Measuring Affective Well-Being by the Combination of the Day Reconstruction Method and a Wearable Device: Case Study of an Aging and Depopulating Community in Japan*, AUGMENT HUM. RES. 1, 3 (2017).

analysis is the insight into the intricate control mechanisms of the autonomic nervous system, in particular the strive to achieve and maintain homeostasis through the competing feedback mechanisms mediated by the sympathetic and parasympathetic subsystems, which HRV analysis is alleged to provide.[98]

C. Caveats Pertaining to the Interpretation of HRV

It has been argued that sympathetic activity is mainly captured by the low-frequency (LF) spectral HRV components while the activity of the parasympathetic subsystem appears to be reflected mainly in the high-frequency (HF) spectral components.[99] Therefore, the LF/HF ratio is commonly used to quantify the degree of balance between the activity of the autonomic nervous system's two subsystems.[100] This is also referred to as "sympatho-vagal balance" and was popularized by Pagani[101] and by Malliani.[102] Its popularity, notwithstanding this interpretation, has been met with harsh criticism.[103] In particular, a paper by Eckberg[104] has received considerable attention and culminated in a vivid discussion among prominent researchers in the field.[105]

Two decades ago, Karemaker[106] stated that "the origin and meaning of HRV are much debated in various circles of researchers"[107] and that "viewing LF as sympathetic and HF as

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[98] *See* Jeremy D. Scheff et. al., *On Heart Rate Variability and Autonomic Activity in Homeostasis and in Systemic Inflammation*, MATH BIOSCI. 8–10 (2017) (for discussion of HRV analysis).

[99] *Id.* at 3, 8–9.

[100] *See id.* at 3, 6 (discussing a case study in which this method is analyzed and used).

[101] *See* Massimo Pagani et al., *Power Spectral Density of Heart Rate Variability as an Index of Sympatho-vagal Interaction in Normal and Hypertensive Subjects*, 2(3) J. HYPERTENS. 383 (1985) (suggesting in the Abstract that there is a link between HRV and sympatho-vagal balance); *see also* Massimo Pagani et al., *Power Spectral Analysis of Heart Rate and Arterial Pressure Variabilities as a Marker of Sympatho-Vagal Interaction in Man and Conscious Dog*, 59 CIRC. RES 178, 190 (1986) (discussing vagal tone).

[102] Alberto Malliani et al., *Power Spectrum Analysis of Heart Rate Variability: a Tool to Explore Neural Regulatory Mechanisms*, 71 BR HEART J 1, 1–2 (1994).

[103] Dwain L. Eckberg, *Sympathovagal Balance: A Critical Appraisal*, 96 CIRCULATION, 3224 (1997).

[104] *Id.*

[105] *See* Alberto Malliani et al., *Sympathovagal Balance: A Reappraisal*, 98 CIRCULATION, 2640a, 2640 (1998) (citing and referring to Eckberg's article several times).

[106] John M. Karemaker, *Heart Rate Variability: Why Do Spectral Analysis?* 77(2) HEART 99 (1997).

[107] *Id.* at 100.

parasympathetic   cardiovascular   control"   would   be   "an oversimplification."[108] Karemaker called for "a limited and cautious interpretation of HRV spectra"[109] and the avoidance of "making unwarranted claims for clinical tests."[110] More recently, Billman[111] concluded that, accumulating evidence clearly demonstrates that this assumption is naive and greatly oversimplifies the complex non-linear interactions between the sympathetic and the parasympathetic divisions of the autonomic nervous system.[112] The LF/HF sympatho-vagal balance hypothesis has been disproven—the preponderance of evidence confirms that LF/HF data cannot accurately quantify cardiac 'sympatho-vagal balance' either in health or disease.[113]

The previously mentioned review paper by Thayer,[114] focusing on the association between HRV and the incidence of various diseases, was heavily criticized by Kluttig[115] who described it as "an example of a biased and unsystematic narrative review of the literature which leads to an overoptimistic appraisal of the association of HRV with cardiovascular risk factors and of the importance of HRV in the development of cardiovascular diseases."[116] For, as the authors state, "studies which showed a consistently inverse association of HRV with mortality, i.e., a higher mortality risk with lower HRV [are contradicted by) several studies which showed that also higher HRV predicts cardiac mortality."[117] Similarly, they dispute that a clear association between biological risk factors, blood pressure, cholesterol, lifestyle factors, moderate physical activity, and HRV has been shown.[118]

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[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *See* George E. Billman, *The LF/HF Ratio does not Accurately Measure Cardiac Sympatho-vagal Balance*, 4 FRONT. PHYSIOL. (2013) (claiming that the LF/HF ratio is not accurate enough to measure cardiac sympatho-vagal balance).

[112] *Id.* at 1.

[113] *Id.* at 4.

[114] *See* Thayer et al., *supra* note 95 (looking at the relationship between HRV and cardiovascular disease risk factors).

[115] *See generally* Alexander Kluttig et al., *Ignoring Lack of Association of Heart Rate Variability with Cardiovascular Disease and Risk Factors*, 145(2) INT. J. CARDIOL 375, 375–76 (2010) (criticizing the optimistic look at HRV and cardiovascular disease risk factors, when authors only looked at favorable studies).

[116] *Id.* at 376.

[117] *Id.* at 375.

[118] *Id.* at 375–76.

Prominent warnings pertaining to the propensity of unfounded inferences drawn from HRV (due to its apparent simplicity) have also been raised in the very guideline that is commonly accepted as reference in the field.[119] In fact, more than two decades ago, the "Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology"[120] unambiguously cautioned researchers that "the significance and meaning of the many different measures of HRV are more complex than generally appreciated and there is a potential for incorrect conclusions and for excessive or unfounded extrapolations."[121]

Concerns have equally unambiguously been raised and reiterated throughout the years, with a particular emphasis on psychophysiology[122] and cardiology.[123] Furthermore, it has been pointed out that despite the widespread use and popularity of HRV analysis in behavioral and psychological science, the psychobiological evidence to date does not provide a sustainable foundation for claims of any simple direction of causality - either that the experience of any particular emotion leads to a consistent and recognizable pattern of cardiovascular activation, or that identifiable and differentiable profiles of cardiac activity are interpreted to be uniquely linked to the subjective experience of specific emotional states.[124]

D. Caveats Pertaining to the Use of PRV as HRV Surrogate

The use of PRV as HRV surrogate further exacerbates the previously discussed problems with HRV by adding additional error and inaccuracy sources.[125] As evidenced in Figure 1, a PPG signal does not exhibit as sharp and pronounced peaks as the ECG

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[119] *See generally Heart Rate Variability: Standards of Measurement, Physiological Interpretation and Clinical Use*, 17 EUR. HEART J. 354–81 (1996) (addressing standards of measurement, physiological interpretation, and clinical use of HRV technology).

[120] *Id.*

[121] *Id.* at 1043.

[122] *See, e.g.*, Gary G. Berntson et al., *Heart Rate Variability: Origins, Methods and Interpretive Caveats*, 34 PSYCHOPHYSIOL. 623 (1997) (noting a recent emphasis on HRV in psychophysiology).

[123] *See, e.g.*, Huikuri et al., *supra* note 92 (addressing the fact that HRV is viable in cardiology but not yet fully adopted).

[124] HANDBOOK OF PSYCHOCARDIOLOGY 9 (Marlies E. Alvarenga & Don Byrne eds., Springer Singapore 1st ed., 2016).

[125] *See* Hayano, et al., *Assessment of Pulse Rate Variability by the Method of Pulse Frequency Demodulation*, 4 BIOMED ENG ONLINE 62 (2005) (discussing PRV's smoother waveform and how that precludes accurate measurements).

does.[126] Pulse peak detection is therefore inherently prone to inaccuracies, which do not arise to the same extent in ECG peak detection.[127] Since the instantaneous heart pulse rate and heart pulse rate variability are by definition derived from the interbeat intervals, this severely limits the use of PPG signals for said purposes.[128]

Furthermore, it is well established that PPG is more sensitive to motion artifacts than ECG.[129] Contrary to ECG measurement setups, where adhesive electrodes, which usually incorporate a conductive gel, are commonly used and guarantee a certain degree of robustness to degradation due to poor contact between electrodes and skin, this is usually not the case with PPG devices.[130] In fact, especially consumer-oriented PPG devices such as wearables heavily compromise optimal probe positioning in favor of consumer expectation, which tends to negatively affect signal quality and stability.[131]

On a physiological level, the predominant cause of discrepancy appears to be attributable to different respiratory modulation mechanisms affecting PR and HR (and thus PRV and HRV)[132]. Schäfer[133] provides an up-to-date review of studies comparing PRV with HRV and concludes that there is significant evidence that short-term variability is overestimated by PRV due to cardio-

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[126] *See supra* Part I for Figure I.

[127] *ECG vs PPG for Heart Rate Monitoring: Which is Best*, NEUROSKY (Jan. 28, 2015), http://neurosky.com/2015/01/ecg-vs-ppg-for-heart-rate-monitoring-which-is-best/.

[128] Mohamed Elgendi et al., *Heart Rate Variability and the Acceleration Plethysmogram Signals Measured at Rest* 266, *in* BIOMEDICAL ENGINEERING SYSTEMS AND TECHNOLOGIES (Ana Fred et al. eds., 2010).

[129] Ahmed Alqaraawi et al., *Heart Rate Variability Estimation in Photoplethysmography Signals using Bayesian Learning Approach*, 3(2) HEALTHC. TECH. LETT. 136, 136 (2016).

[130] *See* Shu-Tyng Lin et al., *A Pulse Rate Detection Method for Mouse Application Based on Multi-PPG*, 17 SENS. 1628, 1628–29 (2017) (discussing that PPG "signal quality is constrained by the position chosen for signal detection."). This article also notes a recent study where PPG sensors were placed on the edges of computer mouse. However, users were forced to physically reach their thumb to the sensor to get a PPG reading. Such a study shows the difficulties associated with PPG sensors and lack of skin contact.

[131] *See* Steven LeBoeuf, *Five Challenges of Optical Heart Rate Monitoring*, SENSORS ONLINE (Feb. 26, 2016), http://www.sensorsmag.com/components/five-challenges-optical-heart-rate-monitoring (noting that many optical heart rate monitoring sensors are located in an area where optical readings are not possible due to "muscle, tendon, bone, and overall arm/wrist movement.").

[132] *See* Isabelle Constant et al., *Pulse Rate Variability Is Not a Surrogate for Heart Rate Variability*, 97 CLIN. SCI 391, 392 (1999).

[133] *See* Schäfer, *supra* note 53, at 15.

respiratory coupling effects and sufficient accuracy can only be achieved when the subject is at rest.

In conclusion, current evidence suggests PRV to be unsuitable as an HRV surrogate in typical wearable and/or health app use cases. This holds especially true when dealing with consumer-grade PPG devices or PPG signals acquired through the use of devices for purposes other than intended (e.g. smartphones), for these devices have not been vetted for such purposes.[134]

E. The Widespread Improper Use of ECG Terminology in the Reporting of Research Findings Based on PPG Data

Despite this clear difference between HR/HRV and PR/PRV, it has become common practice to use these terms as if they were in fact synonymous.[135] The above-mentioned study by Ishio[136] shall serve here as an example of the improper use of terminology in the field. In fact, while it is very likely that Ishio is aware of HRV and PRV not being equal, they fail to address this technicality which, as this Author argues, carries ramifications that ought to be explicitly addressed so as to avoid ambiguity and the very likely "danger" of extrapolations by readers not aware of said peculiarities.

In particular, while Ishio briefly discusses PPG accuracy and reliability problems[137] throughout the paper, he and his co-author report on the use of HRV as derived from a series of R-R intervals, which they claim to have gathered from a commercially available PPG wearable.

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[134] *See, e.g.*, D.S. Quintana et al., *Guidelines for Reporting Articles on Psychiatry and Heart Rate Variability (GRAPH): Recommendations to Advance Research Communication*, 6 TRANSL. PSYCHIATRY 1, 2, 3 (2016) (stating that consumer devices "are generally not formally validated against an ECG for accuracy. Moreover, these devices often (a) report a proprietary metric rather than a standard metric, (b) do not provide access to raw data and (c) do not offer technical details of correction methods (if any are present).").

[135] The Author of this Article wants to emphasize that the following example was chosen merely because it is the most recent peer-reviewed publication reporting PPG-based findings (and resorting to somewhat improper/inadequate terminology) presented in this Article. This is not to question the legitimacy of the work itself; the criticism here is strictly limited to the improper use of terminology. To put the criticism into perspective, it shall also be pointed out that this misuse of terminology is rather common. However, it would be beyond the scope and aim of this paper to further discuss other examples.

[136] *See* Ishio & Abe, *supra* note 98.

[137] *Id.* at 7.

In this research, we decided to use a commercially available PPG sensor ('Mio FUSE') developed by Physical Enterprises Inc. (Mio Global) in collaboration with Philips. Mio FUSE has a PPG sensor named Philips Optical Heart Rate Monitoring Module (OHRM), with enough battery capacity to measure a-day-long RRIs, and a 3-atm waterproof structure.[138] . . . We examined the validity of HRV calculated from the RRI data recorded by Mio FUSE.[139]

By contrast, the FUSE's user manual[140] makes it very clear that the device does not measure R-R intervals and is not suited for HRV analysis.[141] In their discussion of the procedures selected for data analysis,[142] Ishio and Abe reference the "Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology" HRV guidelines,[143] apparently failing to realize that said guidelines assume the use of clinically accurate ECG data. Yet, Ishio and Abe seem to have been aware of the inaccurate nature of their raw data.[144]

Since, by the manufacturer's own admission, the Mio FUSE does not provide R-R interval measurements[145] and, to the best of this author's knowledge, the FUSE's actual algorithms are proprietary and not publicly available, this author can and will only indulge into making an educated guess as to how Ishio and Abe gathered their "RRI" data. Again, this author has no knowledge of the actual computational steps performed by the Mio FUSE. However, given the manufacturer's statement and considering the current academic literature, it appears likely that the Mio FUSE HR estimate is not an estimate of the instantaneous HR (as calculated from the time between two R peaks in the ECG), but rather an estimate extracted through spectral analysis on short excerpts of the signal. This would be consistent with an approach commonly

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[138] *Id.* at 6–7.

[139] *Id.* at 16.

[140] *See* Physical Enterprises Inc., *Mio FUSE - Complete User Guide*, https://mioresources.cdn.commercecm.com/docs/mio_fuse_complete-user-guide en.pdf.

[141] *Id.* at 11. "Heart rate calculation of the Mio FUSE is not based on an instant R-R interval, and will not work for apps and devices that require heart rate variability (HRV) data."

[142] Ishio & Abe, *supra* note 98, at 7–8.

[143] *Id.* at 7.

[144] *Id.* "However, we could not adopt the frequency-domain methods, which require accurate RRI data, because the RRI data recorded by MIO Fuse are possibly averaged/smoothed."

[145] Physical Enterprises Inc., *supra* note 141.

encountered in the literature,[146] wherein a time window of a few seconds in duration (8 seconds in TROIKA) is slid over the PPG signal with incremental steps of about one second (2 seconds for TROIKA). The HR is then estimated through spectral peak detection on the sliding window, yielding a new HR estimate every other second,[147] an averaged/smoothed estimate that is.[148] Thus, quite unsurprisingly, Ishio and Abe failed to achieve satisfactory results in their analysis of affective states based on (what they claimed to be) HRV measurements.[149]

III. LEGAL IMPLICATIONS AND CHALLENGES

A. Classification Uncertainty: Toys, Life-Style Products or Medical Devices?

As accurately pointed out by Van den Bulck in regards to "sleep apps," "many apps and devices avoid being labeled as a medical device, as this would entail undergoing the rigours of approval by government agencies, such as the U.S. Food and Drug Administration."[150] This appraisal is not limited to apps supposedly tracking, influencing, and optimizing sleep patterns, but can be extrapolated to the entire segment of fitness and health-care related apps and wearables.[151]

1. Basics of the Regulatory Oversight over Medical Devices: A German and European Perspective

Focusing on the European perspective, the relevant legislation overseeing medical devices is largely dictated by common European Directives, most notably Council Directive 93/42/EEC.[152] Relevant national legislation in Germany includes

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[146] *See* Zhang et al., *supra* note 33, at 3 (explaining the TROIKA framework); *see also* Schäck et al., *supra* note 71, at 2719 ("The proposed algorithm was constructed to work on sliding windows of 8 seconds and provides a new HR estimate every other second.").

[147] Zhang et al., *supra* note 33, at 8.

[148] Ishio & Abe, *supra* note 98, at 7.

[149] *Id.* at 2.

[150] Jan Van den Bulck, *Sleep Apps and the Quantified Self: Blessing or Curse?* 24 J SLEEP RES. 121, 122 (2015).

[151] *See* Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS HEALTH L. 62, 68 (2016) (for mention of consumer apps); *see also* Susanne Wende, *Teil 17: Gesundheitswirtschaft 4.0* in DIGITALISIERTE WIRTSCHAFT/INDUSTRIE 4.0 196 (2015).

[152] *See* Council Directive 93/42/EEC 1993 O.J. (L 169) (EC) (noting that on April 5, 2017, the European Council and Parliament adopted the new Medical

but is not limited to the Medical Devices Act (Medizinproduktegesetz, MPG), which can be seen as Germany's implementation of 93/42/EEC, and the various related statutory provisions.[153]

§ 3 No. 1 MPG, in accordance with § 1 II (a) 93/42/EEC defines a medical device as:

> (1) any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of a) diagnosis, prevention, monitoring, treatment or alleviation of disease, b) diagnosis, monitoring, treatment, alleviation of or   compensation for an injury or handicap, c) investigation, replacement or modification of the anatomy or of a physiological process, d) control of conception which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.[154]

First, it is important to note the explicit inclusion of software as possibly being a medical device. For the sake of classification, the determining question is whether the product is intended to diagnose, prevent, or monitor a disease or injury.[155] Designation of the device as a medical device is based on its intended use as

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Device Regulation (MDR) 2017/745, repealing the existing Medical Device Directive (MDD) 93/42/EEC discussed here. § 120 MDR provides for a transitional period of three years, so the MDD-based discussion presented in this Article thus remains relevant. Furthermore, changes introduced by MDR do not fundamentally affect the perspective presented in this Article, namely that the vast majority of apps and wearables will continue not to be regularly regarded as medical devices. *See, e.g.* Michael Lang, *Heart Rate Monitoring Apps: Information for Engineers and Researchers About the New European Medical Devices Regulation 2017/745*, 2(1):e2 JMIR Biomed Eng (2017) (discussing the classification of software as potential medical device under MDD and MDR and explaining that with the applicability of MDR still hinging on the device's intended purpose, apps and devices solely intended for lifestyle or well-being purposes do not constitute medical devices under the new MDR); Paul Quinn, *The EU commission's risky choice for a non-risk based strategy on assessment of medical devices*, 33(3) Computer Law & Security Review, 361-370 (2017) (discussing "the problems that are created by the ever-increasing amount of 'well-being' apps and the fact that most will not be classed as medical devices").

[153] These statutory provisions include Medizinprodukte-Verordnung (MPV), Medizinprodukte-Sicherheitsplanverordnung (MPSV), Medizinprodukte-Betreiberverordnung (MPBetreibV), Verordnung über klinische Prüfungen von Medizinprodukten (MPKPV), Verordnung über die Verschreibungspflicht (MPVerschrV), Verordnung über Vertriebswege für Medizinprodukte (MPVertrV), and Allgemeine Verwaltungsvorschrift zur Durchführung des Medizinproduktegesetzes (MPGVwV).

[154] Council Directive 93/42/EEC, *supra* note 153.

[155] *Id.*

stipulated to by the manufacturer on the label of the product, its instruction manual and/or promotional material, and is in fact left for the manufacturer to decide.[156] If the above question, whether the device fits within § 3 No. 1 MPG, is answered in the affirmative, far-reaching implications that exceed those for the placing on the market of an "ordinary" (as in non-medical) device arise.[157]

§ 6 MPG specifies the requirements for a medical device to be placed on the market and to be put into service. Most importantly, the device must bear the CE marking, which in turn demands that the device meets the essential requirements set out in § 7 MPG.[158] §7 MPG has been ascertained to include an assessment of the product's conformity[159] by a designated person or entity in accordance with § 37 I MPG.

Because of such stringent requirements, wearables on the market to date are almost entirely not labeled as medical devices and this is unlikely to change due to case law and the regulatory agency's position on the matter.[160] Two important elements corroborating this forecast will be discussed in the following.

2. Brain Products GmbH v. BioSemi et al

An important "precedent" pertaining to the interpretation of § 3 No. 1 MPG and therefore, by reference, § 1 II (a) 93/42/EEC, was set by the case of *Brain Products GmbH v. BioSemi et al.*[161] The defendant in this case, the Dutch company BioSemi VOF, marketed a biopotential measurement system called "ActiveTwo," which it also marketed and advertised in Germany.[162] The plaintiff, German Brain Products GmbH, which develops and markets hardware and software for biomedical engineering applications, sought an injunction against the defendant to cease

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[156] The Act on Medical Devices, Aug. 2, 1994, at § 3; Council Directive 93/42/EEC, *supra* note 153, at § 1 II(g).

[157] *See* Act on Medical Devices, *supra* note 157 (for requirements for placing medical devices on market).

[158] *See also* Council Directive 93/42/EEC, *supra* note 153, at Annex I (providing a background for the German Medical Devices Act).

[159] *See also* Ordinance on Medical Devices § 7 (referencing the additional statutory information found in the MPV).

[160] *See* Brain Products GmbH v. BioSemi, Case C-219/11 (2012); *see also Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD AND DRUG ADMIN. (2015) (for relevant case law and regulations, respectively).

[161] Brain Products GmbH, *supra* note 161.

[162] *Id.* at ¶ 6.

and desist, and be prohibited from marketing that product since "ActiveTwo" is a medical device and BioSemi and others did not have CE certification for such devices in the Netherlands or in Germany.[163]

BioSemi and others submitted to the court that no such certification was required as their product was not a medical device due to its intended purpose was not for medical use, but rather for research use only, as explicitly stated, among others, on the defendant's website.[164] The defendant also produced a statement from the competent Dutch health authority that acknowledged there was no need for certification of the defendant's product pertaining to 93/42/EEC.[165]

The case was initially argued before the district court, the Landgericht ("LG") Hamburg[166] and—upon dismissal on its merits ("Klageabweisung wegen Unbegründetheit") and the plaintiff's appeal ("Berufung")—the regional court of appeal, the Oberlandesgericht ("OLG") Hamburg.[167] The OLG dismissed the case on its merits as well.[168] Upon further appeal on a point of law ("Revision"), the case landed in front of the Federal Court of Justice, the Bundesgerichtshof ("BGH").[169] In its decision that became known as "Messgerät I,"[170] the BGH decided to stay the proceedings and refer the following question to the European Court of Justice for a preliminary ruling:

> Does a product which is intended by the manufacturer to be applied for human beings for the purpose of investigation of a physiological process constitute a medical device, within the terms of the third indent of Article 1(2)(a) of Directive 93/42/EEC, only in the case where it is intended for a medical purpose?[171]

The 3rd Chamber of the EuGH responded in its ruling as follows:

> The third indent of Article 1(2)(a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, must be interpreted as meaning that the concept

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[163] *Id.* at ¶ 6–7.

[164] *Id.* at ¶ 7*; see also Products*, BIOSEMI, https://www.biosemi.com/products .htm (showing the original notice posted on BioSemi's website).

[165] Brain Products GmbH, *supra* note 161, at ¶ 7.

[166] Bundesgerichtshof [BGH] [Federal Court of Justice] Apr. 7, 2011, ENTSCHEIDUNGEN DES BUNDESGERICHTSHOFES IN ZIVILSACHEN [BGHZ] (Ger.).

[167] *Id.*

[168] *Id.*

[169] *Id.*

[170] *Id.*

[171] Brain Products GmbH, *supra* note 161, at ¶ 10.

of 'medical device' covers an object conceived by its manufacturer to be used for human beings for the purpose of investigation of a physiological process only if it is intended for a medical purpose.[172]

Some further considerations reported in the EuGH's preliminary ruling are worth mentioning. In this decision, the court explicitly provided that "in situations in which a product is not conceived by its manufacturer to be used for medical purposes, its certification as a medical device cannot be required"[173] and gives the example "of many sports goods which enable the functioning of certain organs in the human body to be measured without any medical use. If such articles were to be classified as medical devices, they would be subject to a certification procedure without any justification for that requirement."[174]

This led to the BGH's final ruling in the matter, a decision which in turn became known as "Messgerät II,"[175] wherein the BGH picked up on the EuGH's preliminary ruling and elaborated that an object is not to be labeled as a medical device in terms of § 3 No. 1 MPG and therefore, by reference, § 1 II (a) 93/42/EEC, if its manufacturer excludes a medical purpose clearly enough in the description of the products intended purpose for the targeted audience (i.e., the buyer) to be acknowledged without acting arbitrarily.[176]

3.   The FDA's Regulatory Approach Toward Health Apps and Wearables

The previously stated forecast, namely that wearables and apps for the monitoring of physiological parameters will, in all likelihood, continue not to be regularly regarded and labeled as medical devices, is further corroborated in an international context by the U.S. Food and Drug Administration's (FDA) position expressed in its non-binding recommendations.[177] The FDA's definition of "medical devices"[178] is similar, in fact almost identical, to the European one.[179] In addition, the FDA "intends to

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[172]   *Id.* at ¶ 34.

[173]   *Id.* at ¶ 30.

[174]   *Id.* at ¶ 31.

[175]   Bundesgerichtshof [BGH], *supra* note 167.

[176]   *Id.*

[177]   *See Mobile Medical Applications*, *supra* note 161 (discussing the FDA's stance on wearable technology).

[178]   *Id.* at 7 n.4.

[179]   *See* DG Enter. and Indus. (EC), MEDICAL DEVICES: Guidance Document A.2.1.1(2010) (explaining the European Commission's definition of "medical

apply its regulatory oversight only to those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."[180] The following apps will be subject to its regulation:

- apps that are an extension to already regulated medical devices;[181]
- apps that transform the mobile platform they run on into a regulated medical device;[182] and
- apps that "become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis or treatment recommendations."[183]

Of greater interest (as this will comprise most cases[184]) are those apps where the FDA will exercise its regulatory discretion. The third category comprises apps that augment clinical care by facilitating behavioral changes[185] or maintaining behavioral coping skills,[186] aid patients to keep track of their health information,[187] and calculate simple clinical metrics such as Body Mass Index ("BMI")[188] and apps that allow patients to systematically track relevant treatment progress or events to be discussed with or transmitted to the treating physician, thereby improving doctor-patient communications.[189]

B.   Data Privacy

The mere mention of "IoT" and "Big Data" tends to get privacy advocates up in arms, and perhaps justifiably so. In fact, it may be argued that unsuspecting citizens nowadays are eager to wittingly or unwittingly volunteer data that may eventually be used to their disadvantage and could be very difficult, if not impossible, to delete once it has been disseminated.[190]

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devices").
    [180] *Mobile Medical Applications*, *supra* note 161, at 13.
    [181] *Id*. at 14.
    [182] *Id*.
    [183] *Id*. at 15.
    [184] *See id*. (discussing the times the FDA chooses to exercise enforcement discretion).
    [185] *Id*. at 16.
    [186] *Mobile Medical Applications*, *supra* note 161, at 23.
    [187] *Id*. at 16.
    [188] *Id*. at 17.
    [189] *Id*.
    [190] *See generally* Kim Kommando, *How to Delete Yourself from the Internet,* USA TODAY, (Jan. 25, 2013), https://www.usatoday.com/story/tech/columnist/komando/2013/01/25/komando-delete-yourself-internet/1852143/ (discussing the

First, issues of data privacy inherently beg the question of ownership of the data. Under the legal framework of Germany, the German Civil Code only recognizes property rights pertaining to "things" in terms of § 90 BGB,[191] which implies that, even though ownership can be asserted and protected pertaining to data materialized on a physical storage device, this is not the case for the data itself as it does not qualify as "a thing" in terms of § 90 BGB unless materialized.[192] Thus, ownership under § 903 BGB is excluded.

However, the collection, processing and use of personal data[193] is subject to the provisions of the German Federal Data Protection Act (Bundesdatenschutzgesetz, "BDSG"), whose purpose is "to protect the individual against his/her right to privacy being impaired through the handling of his/her personal data."[194] Circumstances rendering the collection, processing, and use of personal data admissible have been subject to European harmonization under Directive 95/46/EC,[195] where Article 7 provides that personal data may only be processed if, (a) the data subject has unambiguously given his consent; or (b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; or (c) processing is necessary for compliance with a legal obligation to which the controller is subject; or (d) processing is necessary in order to protect the vital interests of the data subject; or (e) processing is

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difficulty attempting to have information about a person removed from the Internet once it has been disseminated).

[191]   *See* BÜRGERLICHES GESETZBUCH [BGB] [Civil Code] § 93 (Ger.) (discussing the property rights of parts of "things").

[192]   *See id.* § 90 (defining only corporeal objects as "things").

[193]   *See* Bundesdatenschutzgesetz [BDSG] [Federal Data Protection Act], Jan. 14, 2003, BGBL I at 66, *amended* by Gesetz [G], Aug. 14, 2009, BGBL I at 2814, § 1 (Ger.) (providing the scope and purpose of the German Federal Data Protection Act as it applies to the collection, processing and use of personal data). Personal data is defined as "any information concerning the personal or material circumstances of an identified or identifiable individual (the data subject)." *Id.* § 3(1). It shall be emphasized that the BDSG and Directive 95/46/EC only apply to personal data as opposed to data pertaining to legal entities, such as corporations or data records from an engine management system.

[194]   *Id.* § 1.

[195]   *See* Council Directive 95/46/EC, 1995 O.J. (L 281) 31, 38–39 (EC) (providing the legislative act that members of the EU follow for data protection); s*ee also* Bundesdatenschutzgesetz [BDSG], *supra* note 194, at § 4 (outlining the requirements to render the collection, processing, and use of personal information admissible).

necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed; or (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under Article 1(1).[196] Thus, under European law, the processing of personal data is generally subject to the so-called principle of "prohibition with the reservation of permission" (Verbot mit Erlaubnisvorbehalt)[197], a popular implementation of which is represented by "opt-in" (as opposed to "opt-out") solutions.[198]

Furthermore, the principles of data reduction and data economy prescribe that "personal data are to be collected, processed and used, and processing systems are to be designed in accordance with the aim of collecting, processing and using as little personal data as possible"[199] and that they "are to be aliased or rendered anonymous as far as possible and the effort involved is reasonable in relation to the desired level of protection."[200] Definitions of "rendering anonymous" and "aliasing" are provided by § 3(6)[201] and § 3(6a) BDSG,[202] respectively, and may, if implemented correctly, result in the admissibility to use the data since it can no longer be attributed to an identified or identifiable person.[203] According to §

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[196]   Council Directive 95/46/EC, *supra* note 196, at 40.

[197]   Christian Solmecke, *Big Data und Datenschutz*, WILDE BEUGER SOLMECKE (Feb. 26, 2013), https://www.wbs-law.de/datenschutz/big-data-und-datenschutz-36177 (explaining that consent provided with other declarations prevails in the practice of opt-in solutions); *see also* Bundesdatenschutzgesetz [BDSG], *supra* note 194, at § 4 (providing that "the collection, processing and use of personal data shall be admissible only if permitted or prescribed by this Act or any other legal provision or if the data subject has consented.").

[198]   *See, e.g.*, Solmecke, *supra* note 197 (explaining that consent provided with other declarations prevails in the practice of opt-in solutions).

[199]   Bundesdatenschutzgesetz [BDSG], *supra* note 194, at § 3a.

[200]   *Id.*

[201]   *See id.* § 3(6) (defining "rendering anonymous" as "the modification of personal data so that the information concerning personal or material circumstances can no longer or only with a disproportionate amount of time, expense and labour be attributed to an identified or identifiable individual").

[202]   *See id.* § 3(6a) (defining "aliasing" as "replacing a person's name and other identifying characteristics with a label, in order to preclude identification of the data subject or to render such identification substantially difficult").

[203]   *See id.* § 3(1), 3a (explaining that "personal data" must concern an identified individual, therefore incentivizing anonymity for maximum protection).

29(1) BDSG, the commercial use of personal data shall also be admissible if "there is no reason to assume that the data subject has a legitimate interest in excluding such collection, storage or modification"[204] or if "the data are retrievable from generally accessible sources . . . unless the data subject clearly has an overriding legitimate interest" in excluding such use[205].

Finally, use of the data is further permitted if the data subject has consented.[206] Note, however, that in such cases, the given consent is limited to the explicitly stated purpose the data subject has consented to, which usually may not comprise later use in "Big Data" applications characterized by an aggregation of large amounts of data from various sources.[207] For, if the specific use of the data was not known a priori, the data subject could not possibly have given an informed consent.[208]

In conclusion, it must be said that the issue of data privacy is bound to remain challenging and controversial especially in light of the proliferation of (wearable) sensors and "Big Data" technology.

C. *Outlook*

There remain numerous open questions and challenges whose discussion would be beyond the scope of this Article. Two of them shall, however, briefly be alluded to.

1. Admissibility of the Data in Legal Proceedings

The inherent limitations discussed above raise concerns regarding the evidentiary value that should be attributed to IoT data, its aggregates and inferences therefrom. If one seeks to introduce such evidence, its reliability needs to be scrutinized to determine whether it is akin to forensic evidence or expert witness testimony.[209] As of today, the data produced and especially the

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[204]   *Id*. § 29(1), no. 1.

[205]   Bundesdatenschutzgesetz [BDSG], *supra* note 194, at § 29(1), no. 2; *see also* Solmecke, *supra* note 198 (confirming that the collection of publicly accessible data is permissible unless "the legitimate interests of the data subject are justified by the interests of the data subject").

[206]   *See id*. § 4a (delineating the proper use of consent with regard to the collection, processing and use of a data subject's information).

[207]   *See* Solmecke, *supra* note 197 (explaining that there is "a multitude of possible uses" with regard to the use of personal data in "Big Data" companies).

[208]   *See id*. (acknowledging the requirement that consent must be voluntary and specifically reference the purpose of the data collection, processing, or use).

[209]   Katherine E. Vinez, Comment, *The Admissibility of Data Collected from*

inferences or rather speculations made on their basis will not generally hold up to such a high level of scrutiny.[210]

2. Regulation by Litigation: Will Product Liability Lead to a Solution?

Even though by avoiding to be classified as a medical device a product and its manufacturer are not subject to the same level of scrutiny, the manufacturer (first and foremost, but possibly other agents as well) is still liable for damages caused by its defective products.[211] Furthermore, consumers may raise claims under contract law if the product is not suitable for the customary use and of the quality a reasonable buyer would expect from a product of this kind.[212] It is therefore safe to assume that "regulation by litigation" will shape the health apps and wearables industry in the foreseeable future.[213]

CONCLUSION

Despite overly optimistic appraisals, the field of smart wearable devices and apps faces a plethora of technical challenges and limitations. This Article gave an overview of the state of the technology and argued that optical HR monitoring through PPG is currently unable to provide accurate and reliable results under actual real-world circumstances, with even greater problems on the horizon as the industry shifts towards areas such as heart rate variability monitoring or the detection of cardiac arrhythmias.

Further, this Article showed that overly simplistic and unfounded physiological modeling assumptions further exacerbate issues of inaccuracy.

Moreover, the fact that health and fitness related apps and wearables on the market to date are almost entirely not labeled as medical devices was discussed, and it was argued that this is unlikely to change anytime soon, as has been shown by examining

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Wearable Devices, 4 STETSON J. ADVOC. & L. 1, 8, 23 (2017).

[210] *Id.* at 5, 8.

[211] *Fitness Trackers Involved in Products Liability Lawsuits*, TATE LAW GROUP, http://tatelawgroup.com/fitness-trackers-involved-products-liability-lawsuits/.

[212] U.C.C. § 2–315. "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose."

[213] *Cf.* Terry & Wiley, *supra* note 151, at 97.

relevant case law and regulatory agencies positions on the matter.

This Article also briefly elaborated on the extensive body of applicable data privacy provisions and discussed the increasing issue of products liability in this arena.