# Electronic gadgets and their health-related claims

by

Marek Malik, PhD, MD1, A John Camm, MD2, Heikki Huikuri, MD3, Federico Lombardi, MD4,
Georg Schmidt, MD5,6, Peter J Schwartz, MD7, Markus Zabel, MD8
on behalf of e-Rhythm Study Group of EHRA

**(1)** National Heart and Lung Institute, Imperial College, London, England,
**(2)** St. George’s University of London, London, England,
**(3)** Research Unit of Internal Medicine, University of Oulu and University Hospital,
Oulu, Finland,
**(4)** IRCCS Policlinico, University of Milan, Milan, Italy,
**(5)** Klinik für Innere Medizin I, Technical University of Munich, Munich, Germany,
**(6)** DZHK, Partner site Munich Heart Alliance, Germany,
**(7)** IRCCS Istituto Auxologico Italiano,
Center for Cardiac Arrhythmias of Genetic Origin and Laboratory of Cardiovascular Genetics, Milan, Italy
**(8)** Department of Cardiology and Pneumology - Heart Center,
University of Göttingen Medical Center, Göttingen, Germany

*Short title:* **Electronic gadgets and medicine**

**The authors report no relationships that could be construed as a conflict of interest**

*Address for correspondence*:

Marek Malik, PhD, MD,
NHLI, Imperial College,
London SW3 6LY, England

marek.malik@btinternet.com

This commentary responds tothereport by Guziketal[1] showing that heart rate variability (HRV) indices provided byequipment forexercise tracking aredifferent from those based onproper ECG analysis. Whilst this observation is not surprising, itbrings aquestion of theaccuracy and reliability ofhealth-related claims byunregulated personal gadgets. Naturally, this goes beyond HRV and concerns many devices that members ofpublic purchase for avariety ofreasons. Anecdotes about nonsensical reports by small gadgets are numerous butare such cases easily dismissed orshould we be more concerned?

We presently experience anunprecedented data explosion. IBM Consumer Products Industry Blog states that 2.5exabytes (millions of terabytes) are produced every day[2]. Undoubtedly, some of these data benefit our lives substantially. Nevertheless, various social media show that agood part of thedata hasonly minute interim and nolong-term value. This also concerns images and signals obtained byrecreational devices attached or otherwise linked to human bodies. While some devices and their applications offer only entertainment, others are used because of claimed orassumed health-monitoring or even medical benefits. There is abroad spectrum oftechnology involved and some devices offer valuable help inhealthcare delivery and/orclinical monitoring[3]. Some others, however, are associated with highly dubious claims orsuggestions.

Heart rate monitoring and cardiac cycle detection is agood example todemonstrate this spectrum ofapproaches. Devices that collect theelectrocardiogram[4] and allow thesignal to be reviewed and its interpretation edited are comparable to commercial Holter systems using thesame leads. Devices that use different technology such as plethysmography or other optical sensors are likely tobe less accurate, especially ifrecorded signals cannot be reviewed and thedetection of cardiac cycles verified[5]. Necessarily, thedistinction between valid and invalid signals isless accurate than that based on an electrocardiogram and related accuracy claims can bebitterly disputed[6].

Thesituation gets further complicated if thedetection of cardiac periods is used not for simple heart rate monitoring but formore elaborate purposes such asdetection ofatrial fibrillation orHRV evaluation. The dependency ofHRV assessment accuracy on the source RR data quality is well known[7]. Approximate algorithms suggested for24-hour HRV assessment without theneed for distinguishing sinus and ectopic beats are used in implanted devices[8]. Nevertheless, no approximate algorithms exist tocope with RR data that, inaddition toectopics, may omit some beats and misinterpret noise. Ifsuch data are used toprovide short term HRV, theresults can hardly be trusted at their face value. In this sense, thereport by Guziketal[1] isnot surprising. Interpreting the numerical results reported by Guziketal, we also note that they investigated healthy subjects in arelatively noise-free environment and used amonitoring device that was found, under these conditions, tobe more accurate compared tosome other gadgets[5]. Data quality would likely be more problematic in cardiac patients in whom rhythm abnormalities are more frequent but in whom autonomic assessment during provocations might be ofclinical value. Likewise, the accuracy of HRV reported by optical sensors-based devices would probably also belower.

Guziketal also show that, to paraphrase politicians, there are both known andunknown unknowns inthe signal acquisition combined with data elaboration bythe new technologies. Without substantial disclosures from themanufacturers, we cannot know whether the discrepancies come from incorrect detection ofcardiac cycles orfrom thepostprocessing application. Moreover, without proper testing, wecannot even guess the response of this technological combination torhythm pathologies that should not bemissed (e.g. ventricular tachycardia, atrial fibrillation, asystole,etc.) Only themanufacturers might know whether processing of such signals has ever been attempted.

Ifapproximate HRV reporting is used for entertainment purposes, e.g.to guess autonomic reactions toheavy meals, sexual activity, yoga, orcomputer games, notmuch actual harm exists. However, if apatient previously warned about problematic lifestyle and risks ofischaemic disease complications uses some ofthese approximate HRV monitors as an assurance of good cardiovascular health, the danger of serious medical complications becomes very real. Similarly, if agadget warns apsychologically sensitive individual oferroneously abnormal HRV measurements, potential adverse consequences may result.

This all goes obviously well beyond cardiac rhythm monitoring and HRV assessment. There is adifference between the implications that the data generated bypersonal devices may have for healthy subjects and for patients who might be misinformed about their condition. Frequently, regulatory bodies distinguish between devices intended for medical and non-medical purposes, per manufacturer’s declaration. Only manufacturers ofmedical devices (diagnosis or therapy related) need to enable accuracy validation byproviding raw data access. Devices intended for non-medical use (sport, fitness, well-being, nutrition, etc) are frequently exempt. However, such recreational devices are alsoused by patients and their inaccuracy may substantially influence personal medical decisions. This is anobvious reason forconcern.

In this sense, medicine-related statements bysome ofthe manufacturers of modern personal gadgets are reminiscent ofthe old days ofunregulated pharmaceuticals when any snakeoil could have been advertised for whichever ailment. Similarly to pharmaceutical safety, this should not beallowed tocontinue and improvement in three separate areas may be proposed.

Firstly, the general public needs tobe educated to understand that there are substantial differences between properly regulated medical equipment and unregulated recreational gadgets. The differences between over-the-counter pharmaceuticals and food supplements are hopefully well understood. Nevertheless, contrary tofood supplements, there is noindependent safety regulation presently involved in settingup these electronic gadgets and applications. Relying on unregulated devices inpersonal medical decisions islike accepting treatment from alternative healers.

Secondly, the matter of gadgets associated with various health assessment functions that might lead to potential medical implications should becarefully considered by regulatory bodies irrespective of the explicit manufacturer’s claims. Being responsible for controlling the guidance to the public, the regulators should remember that “The theories of the accredited scientist and ofthe quack are alike tothe eyes ofthe gullible beholder”[9]. Small print warnings that the device/application isonly for entertainment or similar purposes should not imply the possibility ofhinting at non-validated medical advantages. For instance, returning toHRV, noreference tothe clinical value ofHRV assessment should be allowed in adevice description if the provided measurements are only roughly approximate.

Finally, the producers of the equipment and associated applications should realise that only independent thorough testing by properly qualified groups and institutions can constitute a basis for not only making medical claims but also suggesting health-related advantages. Similarly to pharmaceutical testing, acomprehensive spectrum of tests needs to be applied to validate any assertions. Having such independent professional validation might eventually save theproducers during difficult litigation[6].

# Acknowledgments

Supported in part by the British Heart Foundation (NH/16/2/32499), and by the European Community's Seventh Framework Programme (FP7-HEALTH-2013-INNOVATION-1 #602299).

# References

1. Guzik P, Piekos C, Pierog O, Fenech N, Krauze T, Piskorski J, Wykretowicz A. Classic electrocardiogram-based and mobile technology derived approaches to heart rate variability are not equivalent. Int J Cardiol 2018; ??:??-??.
2. https://www.ibm.com/blogs/insights-on-business/consumer-products/2-5-quintillion-bytes-of-data-created-every-day-how-does-cpg-retail-manage-it/ accessed 24/01/18
3. Ziegler PD, Glotzer TV, Daoud EG, Singer DE, Ezekowitz MD, Hoyt RH, Koehler JL, Coles J Jr, Wyse DG. Detection of previously undiagnosed atrial fibrillation in patients with stroke risk factors and usefulness of continuous monitoring in primary stroke prevention. Am J Cardiol 2012; 110:1309-14.
4. Guzik P, Malik M. ECG by mobile technologies. J Electrocardiol 2016; 49:894-901.
5. Gillinov S, Etiwy M, Wang R, Blackburn G, Phelan D, Gillinov AM, Houghtaling P, Javadikasgari H, Desai MY. Variable accuracy of wearable heart rate monitors during aerobic exercise. Med Sci Sports Exerc 2017; 49:1697-703.
6. http://time.com/4344675/fitbit-lawsuit-heart-rate-accuracy/ accessed 24/01/18
7. Malik M, Xia R, Poloniecki J, Odemuyiwa O, Farrell T, Staunton A, Camm AJ. Influence of the noise and artefact in automatically analysed long term electrocardiograms on different methods for time–domain measurement of heart rate variability. Proceedings Computers in Cardiology 1991; IEEE, Los Alamitos: 269-272.
8. Malik M, Padmanabhan V, Olson WH. Concepts of an automatic measurement of long term heart rate variability by implanted single chamber devices. Med Biol Eng Comput 1999; 37:585-594.
9. Froggatt P. A cardiac cause in cot death: a discarded hypothesis? Ir Med J 1977; 70:408-14.