Instrumentation and Measurement in Medical, Biomedical, and Healthcare Systems

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Proper measurement is crucial in the medical, biomedical, and healthcare fields because it forms the basis of medical diagnosis, prognosis, and evaluation. In fact, it is known that "measuring is the cornerstone of medical research and clinical practice" [1]. Medical professionals such as doctors or clinical laboratory scientists must have confidence in the results reported by their instruments or their measurement methods to make the correct decision for their patient. While in many industries incorrect measurements would simply lead to customer dissatisfaction or loss of money, in the medical field incorrect measurements could be fatal and lead to loss of life. Hence, we can say that proper instrumentation and measurement is vital in the medical field.

In this article, we take a look at the latest biomedical topics from the perspective of Instrumentation and Measurement (I&M), and we summarize the latest medical I&M topics published in *IEEE Transactions on Instrumentation and Measurement* (TIM), to familiarize medical practitioners and researchers in how to achieve a proper medical I&M paper. We also briefly introduce the IEEE Instrumentation and Measurement Society's (IMS) main medical conference, the IEEE Symposium on Medical Measurements and Applications (IEEE MeMeA), which promotes the I&M aspects of the medical field in general, and we present guidelines on the I&M aspects that are useful for authors with primarily biomedical backgrounds who would like to publish in IEEE TIM.

Introduction

I&M as a field is primarily interested in measuring, detecting, monitoring, and recording of a phenomenon referred to as the measurand, and associated calibration, uncertainty, tools, and applications. The fundamentals of I&M apply to any kind of instrument or measurement, including medical ones. As such, it is not surprising to see that IEEE TIM, the flagship journal of the IMS, receives a significant number of submissions in the medical field. Many of the submissions are in medical imaging, which we consider part of Vision Based Measurement, a subject area already discussed in another overview article [2]. The remaining submissions, especially in recent years, are mostly in the subject areas of physiological monitors and sensors, and health parameters monitoring, which are the subjects of this article. It is not surprising to see more submissions in these specific subject areas because of the ever-increasing advancements in today's mobile devices with touchscreens, context monitoring, voice and gesture recognition, etc., which has created a boom in their usage in medical applications.

It should be noted that this article is meant as an overview only and we cannot cover in detail the complete range of I&M aspects in the medical field: measurement accuracy, uncertainty, instrument reliability, calibration against the gold standard, and complying with various regional, national, or international medical regulations. With this in mind, let us start by looking at physiological monitors and sensors from an I&M perspective.

Physiological Instruments

The technological revolution in recent years has opened opportunities for bringing medical facilities to everyone's home doorstep. This is realized not only by numerous apps available for smartphones, such as [3] and [4], but also by specialized devices, which are provided in portable format. For such devices, two major open questions arise for the I&M community:

- How can we safeguard that the clinical quality of measurements is achieved using the low cost measurement equipment in a home environment? and
- How are abuse and misusage avoided when medical devices are brought into a home environment and then operated by a lay user?

The most important key to solving these questions is to enhance the signal quality. Since specialized equipment forces the price extremely high, inexpensive low cost equipment can be equipped with advanced signal processing tools, which are not expensive. In addition, specialized sensors can be replaced by lower cost sensors or measurement devices, which a layperson can operate that have a dedicated mathematical model or data analysis technique that can compute the physiological parameter of interest from the acquired measurements.

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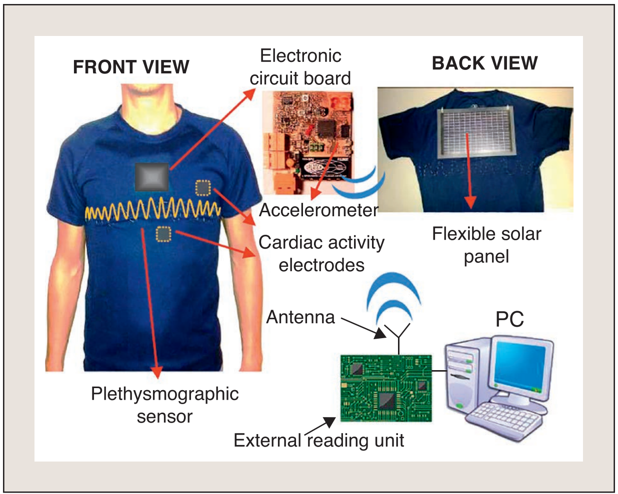

Fig. 1. Energy harvesting for wearable sensors. (© 2016 *IEEE, Trans. Instrum. Meas.*, used with permission, [6].)

The following are some examples of works published in TIM where this philosophy and goals are shared.

Physiological Monitoring of Gait

Movement measurements for gait monitoring are crucial for both prospective walk assistance devices and for artificial limbs. In [5], forces applied to crutches are measured, and a wireless transceiver system is added to the crutches to observe the gait and allow for centralized analysis. However, physiological monitoring goes beyond the scope of recovering and assistance.

Wearable Sensors

Simply imagine athletes or recreational sport activities where there is a big demand to accurately monitor heart rate, oxygen saturation, blood pressure, and step count. Besides this type of monitoring, there is also a demand that such devices must be fashionable and as invisible as possible. This dictates the use of wearable sensors or sensors integrated in clothes. Accurate measurements need computer power, which imposes a challenge on energy consumption and storage for wearable sensors. One may consider the use of energy harvesting through, for instance, tiny solar panels to continuously support the measurement devices. In the design of such energy harvesting methods, one must also ensure low power consumption vital sign monitoring. This particular problem is discussed in [6], as Fig. 1 shows.

Artefacts and Noise in Wearable Sensors

Wearable sensors, however, create other problems. For example, the measurements are less controlled in the sense that they easily get contaminated by artefacts, in addition to random noise. Artefacts like movement errors are deterministic and result in a bias, while random noise results in large uncertainty and error bounds but typically should not introduce a systematic error. Artefact bias can also happen due to inter-patient variability and disturbing vital signals like the breathing signal, which we must take into consideration. Even a simple thing like the amount of pressure on wearable ECG electrodes can drastically change the measured biosignal [7]. From a measurement viewpoint, one is interested in feature detection to isolate specific signal patterns, artefact removal and, for instance, denoising. Inter-patient variability may be problematic but can also be turned into an advantage. One may consider that *physiological signals could uniquely identify a specific individual*, leading to biosignal authentication as a new emerging field. In this aspect, from a measurement perspective, one wishes to extract specific patterns or artefacts in biosignals which are unique to that specific person. For instance, in [8], an authentication procedure is presented based on the electrocardiogram (ECG), by identifying specific patterns and features in the ECG, which allow identification of people.

Advanced Signal Processing Techniques

At the other side of the spectrum, such specific features are unwanted signals, such as respiratory and vasomotive waves which are physiological noise and undesirable. To have a cleaner physiological signal, advanced signal processing techniques are currently being studied which take into consideration that:

- biosignals are often non-stationary but are
- multi-frequency signals where the harmonics give important biomedical insight.

This implies that processing or signal analysis must perform an approximation, like Fourier series analysis, while properly handling the non-stationarity nature, like wavelet transforms can do. Short Time Fourier Transform (STFT) has been the state of the art technique to obtain the aforementioned compromise but raises problems of automation. In particular, STFT requires both the frequency and time resolutions and both cannot be optimized simultaneously.

In an effort to generalize the classical Fourier analysis, efforts such as [9] study the Taylor-Fourier analysis for analyzing near-infrared spectroscopy as a neuro-imaging technique: an alternative to the well-known magnetic resonance imaging (MRI) technique. Advanced machine learning techniques have also been applied to study biosignals and biomedical measurements like neural networks and support vector machines. For instance, in [10], support vector machines were applied to assess the quality of the measured biosignals where particularly contaminated electromyography signals were classified as a function of their quality.

Oscillometric BP Monitors

The IEEE IMS has also shown significant interest in more accurate oscillometric blood pressure monitors which a user can operate in a home setting. In fact, IMS Technical Committee 25 (TC-25) "Medical and Biological Measurements" has a subcommittee on "Blood Pressure Measurement" that is currently working on IEEE Project P1721: "Standard for Objective Measurement of Systemic Arterial Blood Pressure in Humans" (https://standards.ieee.org/develop/project/1721.html). Such a project is needed because the main problem with current blood pressure monitors is that the blood pressure is not

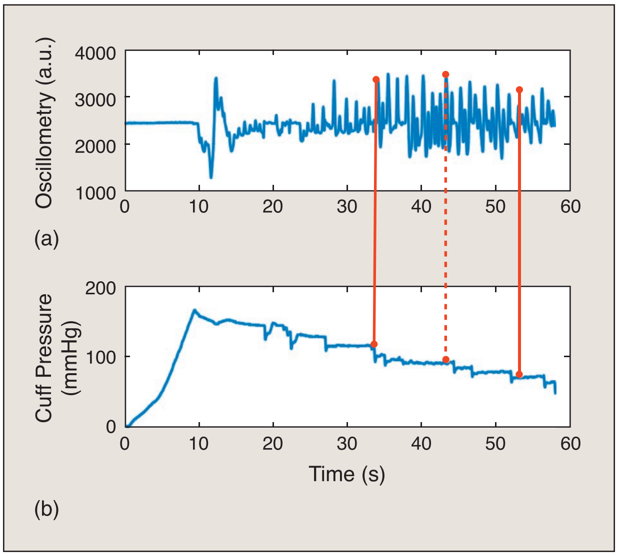

Fig. 2. Comparison of blood pressure measurement methods. (a) Measured oscillometric waveform with a noninvasive blood pressure amplifier, and (b) the corresponding pressure wave in the PPG cuff. The left and right solid red vertical lines give the systolic and diastolic blood pressures, respectively, from the dashed vertical line that denotes the mean arterial pressure.

measured but computed from characteristics and features in the oscillometric waveform.

Classically, the envelope of the oscillometric waveform was considered to determine the blood pressure, and this has been implemented commercially through several algorithms. These algorithms try to identify from the envelope of the oscillometry three time instants (as shown in the example in Fig. 2): the first time instant corresponds to the systolic pressure, the second time instant corresponds to the mean arterial pressure (MAP), and the third time instant corresponds to the diastolic pressure. Recently, that viewpoint was revised and more thoroughly investigated leading to important new insights, for instance in [11], where higher harmonics measured with a lower S/N ratio hold physiological information. Such higher harmonics and mixing products were considered in [12] and [13]. In addition, the classical envelope based techniques were revisited in an effort to improve their results. In [14], Gaussian mixture regression is added to the envelope based techniques, while in [15], additional measurement equipment was applied to compare the oscillometric devices to the Korotkoff golden standard and obtain an overall improved blood pressure determination.

Biomedical signal acquisition using imaging wearable sensors and home monitoring implies a need for low cost ADCs for measurement equipment. This implies that researchers must give specific attention to lossless compression schemes and integrate-and-fire samplers among others. In [16], the author presents a compression method for real-time measurement acquisition of photoplethysmogram (PPG) signals at a commercial sampling rate of 125 Hz using a 10-bit quantizer. In particular, the work studies the obtained quality of the features, which are physiologically relevant. A similar study was performed for ECG in wireless transmission [17] where, besides reconstruction accuracy, an energy efficiency constraint was also taken into consideration.

Monitoring Health Parameters

Once we have the proper physiological instruments, we can use them for continuous and ubiquitous health monitoring; i.e., applications of these instruments. One example is [18], where an improvement of the measurement evaluation used during sports activities in real-time is introduced. Health monitoring and sport activity risk calculation can be very useful to avoid emergency situations. Using these kinds of applications, the necessary alarm signals can be raised in time and could potentially save lives. Recent literature in the area of health parameters monitoring has highlighted an increasing interest in improving the quality of life. Future research in this area must:

- give emphasis to the accuracy and reliability of each health-care application,
- highlight strong and weak points with respect to the traditional medical devices and techniques, and
- deduce why it could be a valid alternative with respect to existing specialized medical devices in the case of home-based and self-monitoring.

In this section, we look at some applications in monitoring heart rate and blood pressure, blood oxygen saturation, respiratory system, patient positions and transitions, as well as home-based rehabilitation.

Monitoring Heart Rate and Blood Pressure

For many patients, the daily monitoring of the heart rate (HR) and blood pressure (BP) could lead to reduced mortality risk. The presentation of a promising approach to avoid the well-known white coat syndrome where a patient exhibits high BP only in a clinical setting is in [19]. A camera acquires a PPG signal containing information about the cardiovascular system, including BP. By evaluating the PPG at the same time, it is possible to obtain other important parameters such as the HR, which can provide more information about the health status of the user. Each PPG pulse has a heart pulse and a venous pulse; therefore, by analyzing the time intervals between two consecutive heart pulses, it is possible to determine the HR.

Monitoring Blood Oxygen Saturation

Blood oxygen saturation (SpO2) is important for patients affected by chronic pulmonary and cardiovascular diseases. They require knowing the SpO2 concentration to set the oxygen flow properly. This therapy is performed not only in clinics or hospitals but also for patients at home. Moreover, healthy people during hard training exercises have to know whether they are in hypoxia. Traditional solutions for the SpO2 concentration measurement are the gas chromatograph, which is the gold standard, and the pulse oximeter. The gas chromatograph analyses arterial blood extracted by a specialized clinician. The pulse oximeter performs non-invasive measurements based on the properties of the oxy-hemoglobin (HbO) and deoxy-hemoglobin (Hb) to absorb, in different manners, the light at different wavelengths. It is equipped with two light

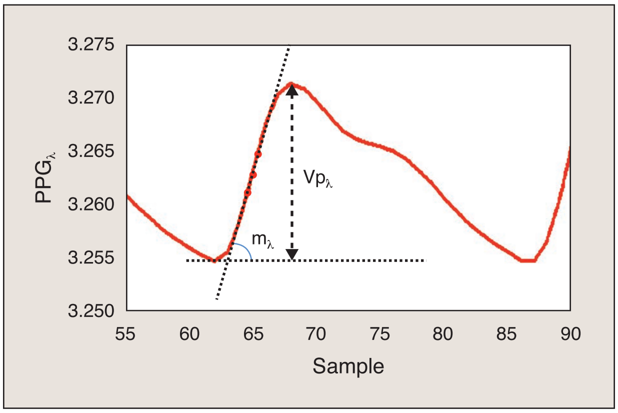

Fig. 3. Shape parameters Vp_λ and m_λ evaluated on a single PPG pulse (© 2015 IEEE, *in Proc. IEEE Int. Symp. Medical Meas. App.*, [20].)

emitting diodes (LED) at infrared (940 nm) and red (600 nm) wavelengths that detect PPG signals related to HbO and Hb. The SpO2 concentration is the ratio between the molar concentration of HbO and Hb. Both HbO and Hb are correlated to the shape parameters of the PPG pulse, as Fig. 3 shows: the rising edge slope m_λ and the peak-to-peak voltage Vp_λ. The SpO2 concentration is evaluated in [21] without the calibration factor and independently of hardware and skin characteristics, by using the absorption coefficient of HbO and Hb.

Monitoring the Respiratory System

A preventive and continuous monitoring of the respiratory system proves necessary for many patients. A proposal to detect the sleep apnea hypopnea syndrome (SAHS) using the performance of an unobtrusive sleep monitoring system is in [22]. The proposed system is a pressure bed sensor (PBS) that incorporates multiple pressure sensors into a bed mattress to measure several physiological signals of the sleeping subject: respiration, heart rate, and body movements. PBSs could be used to evaluate different sleep pathologies, such as SAHS, insomnia, periodic leg movement, and cardiac dysfunctions. The proposed analysis is only based on the respiratory effort in association with the activity signal.

Monitoring Patient Positions and Transitions

The demand for geriatrics, specifically the automated assessment of older adult health, is rising very fast due to the aging population and demographic shift in industrialized countries. Mobility is considered an indicator of health for the elderly and is more tangible than some other health measures. In [23], we see a system of algorithms aiming to automatically identify discrete and continuous patient positions and transitions. In particular, the system identifies and distinguishes between and explores pressure signals resulting from three positional states and three corresponding state transitions.

Home-Based Rehabilitation

Home-based rehabilitation has evolved in recent years as a cost-effective and convenient alternative to traditional clinical rehabilitation. This has consequently created the need to design reliable assessment and adaptation mechanisms that are able to measure and analyze the patient's performance and accordingly make proper adjustments that conform to the abilities of the patient during the training. In [24], a home-based rehabilitation framework is presented. To offer therapy training that can properly adjust to the performance of the patient, the adaptation should not be based only on the patient's physical state but also on his/her psycho physiological and environmental conditions.

IEEE MeMeA

The idea of a conference merging the fields of instrumentation and measurement with biomedical engineering came from the increasing success of the special sessions on "Medical Measurements and Applications" organized by the aforementioned TC-25 during several IEEE International Instrumentation and Measurement Technology Conferences (I_2MTC) since 2000. To provide more space and time for discussions for a growing community of researchers and to open it to scientists coming from fields different than engineering, like medicine, biology, and chemistry, TC-25 spun off a dedicated event called "IEEE International Workshop on Medical Measurements and Applications (MeMeA)" that was held for the first time in Benevento, Italy, in 2006. Due to the success of that inaugural event, MeMeA continued in the following years in Warsaw (Poland), Cosenza (Italy), and twice in Ottawa (Canada). In 2011, following the ever increasing number of attendees, the workshop became a symposium with its editions in Bari (Italy), Budapest (Hungary), Gatineau (Canada), Lisbon (Portugal), and Turin (Italy). This year, after ten successful editions, MeMeA returned to where it was born: Benevento (Italy), and in 2017 the Symposium will move to the USA for the first time to be held at the Mayo Clinic in Rochester, Minnesota.

The increasing number of scientists who attend MeMeA and who come from fields that can be very far from engineering has led to a positive hybridization of knowledge and experience. The conference now presents the state of the art in the research for I&M in medicine, assembling researchers from universities and industries interested in developing novel solutions to instrumentation and measurement problems encountered in modern healthcare. Therefore, MeMeA is dedicated to all aspects of the intersection between I&M and the medical field, with the aim of highlighting how measurements represent a real challenge for collecting correct and trustworthy data for patients in medicine and healthcare.

As described by Galileo in the 16th century, "Measure what is measurable, and make measurable what is not so." All branches of science need to use measurement and most of them need to design measurement methods and instruments, also. Looking back at Lord Kelvin's famous citation, "To measure is to know," most of scientists' interest in measurement focuses on answering a utility question: "How can I get the quantitative information about reality in order to make the correct decision?" To that aim, researchers in their respective fields continue to design new instruments with increased robustness, lower cost, and higher usability and utility.

As a result, all researchers sooner or later have to provide a satisfactory answer to two basic and fundamental questions. The first question is "How reliable and useful is the information I can obtain about reality?" Stated more formally, one could ask: "Provided that there is a way to obtain quantitative information about a property, phenomenon, process, or object under study, is there a way to know how much I can trust this information?" This way of expressing the problem introduces the second fundamental question "What is the uncertainty in my measurement results?" To trust a measurement result, one must be able to trace it to a recognized standard and to provide its accuracy, where accuracy is most appropriately expressed by uncertainty [25]. In medical measurements, both questions must be answered at the same time: traceability of instruments is a necessity but is not a sufficient condition to ensure reproducibility of experiments, while uncertainty is the quantitative assessment of the degree of unknown about the results and can never be removed [26]. However, for the medical field, both traceability and uncertainty mean nothing if the results are not useful in making the correct decision about the medical problem; i.e., about what to do with the patient, the illness, etc. These topics are of great interest and given emphasis at MeMeA.

The success of MeMeA can be attributed to the diversity of its attendees: measurement specialists, electronic and bioelectronic equipment designers, and medical users of measurement methods and instrumentation, who share their points of view, experiences, and results in various areas such as sensor design and calibration, instrument and virtual instrument design and calibration, measurement methods, analysis of measurement results, and image and signal processing based measurement for medicine. In short, MeMeA is where new joint multidisciplinary and international research groups glue together I&M and biomedicine. Due to this interdisciplinary nature, and to encourage non-I&M researchers to attend the symposium, benefit from it, and to get an education about I&M as applied to the medical field, MeMeA's scope is purposely kept broad somewhat beyond I&M limits. But the same cannot be said about MeMeA's annual Special Issue in IEEE TIM [27]: while authors of accepted MeMeA papers are encouraged to technically extend their work and submit as a journal paper to this special issue, it is crucial for these authors to understand that their submission must strictly adhere to the I&M scope set by IEEE TIM, as discussed next.

TIM Guidelines for Medical Related Papers

It is very important for the medical community to understand when a work in this field belongs mainly to pure biomedical engineering and when it can be considered within the I&M field. Let us consider TIM as an I&M venue to which, as already stated above, medical papers are submitted and published regularly. TIM's scope is defined to encompass research papers:

> *… that address innovative solutions to the development and use of electrical and electronic instruments and equipment to measure, monitor and/or record physical phenomena for the purpose of advancing measurement science, methods, functionality and applications.*

A paper submitted to TIM must therefore:

- clearly show how it satisfies the requirements above,
- must cover the related recent literature in the field of I&M,
- position its own contribution with respect to those literature, and
- compare itself either analytically or experimentally with existing methods, techniques, and applications in the field of I&M.

As such, while at TIM we certainly encourage submission of medical, biomedical, and healthcare papers, we do not consider papers whose core contribution is strictly in the medical aspects without any clear I&M context. For example, a paper that proposes a new imaging technique to detect cancerous cells, without any direct I&M context, without characterizing the proposed technique in terms of measurement uncertainty, and without analytically or experimentally comparing the technique to existing I&M literature on the subject, will not be considered at TIM. At TIM, we redirect such papers to more appropriate journals, such as, *IEEE Transactions on Biomedical Engineering, IEEE Transactions on Medical Imaging,* or *IEEE Journal of Biomedical and Health Informatics*.

At TIM, we only consider medical papers that have I&M as their core contribution. For instance, a paper that proposes a new imaging technique to detect cancerous cells and then shows experimentally that the proposed technique can detect cancer cells more accurately than existing and recent I&M based techniques, as proven by uncertainty measurements, will be considered at TIM. From an I&M perspective, any new measurement technique becomes useful if and only if it brings increased accuracy or increased computational or economic efficiency with the same accuracy.

Conclusions

In this article, we discussed the importance of I&M for the medical, biomedical, and healthcare fields, and we explained some of the I&M aspects from which these fields could benefit. We also covered examples of some related I&M literature, introduced the IEEE MeMeA Symposium, and described the criteria for a journal paper in these fields to be considered at IEEE TIM. As mobile devices and computing become ever more ubiquitous and affordable, we expect to see even more research or practical work in this area, leading to more results in the form of papers, prototypes, and products.

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