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Research review paper

Powering point-of-care diagnostic devices

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ABSTRACT

Effective and rapid point-of-care (POC) diagnostics have the capability to revolutionize public healthcare both in developed and developing countries. One of the key challenges that is critical to address in developing POC devices is to effectively and sufficiently power them. In developing countries, where the electricity grid is not well established and the use of batteries is not cost-effective, power supplies are the most problematic issue for stand-alone and self-sustained POC devices. In this review, we provide an overview of techniques for powering POC diagnostic devices for use in both developed and developing countries, as well as detailed discussions of recent advancements in POC devices. Then, we discuss next-generation POC diagnostics and their power source strategies.

Contents

1. Introduction

Accurate and rapid disease diagnosis is critical to providing the most effective and life-saving treatments in a timely manner. In developed countries, traditional and modern diagnostic tests are usually performed at central laboratories equipped with sophisticated molecular analyzers and high-resolution imaging techniques (Yager et al., 2006; Sin et al., 2014; Jung et al., 2015). Those laboratories have established test protocols and step-by-step procedures to improve efficiency and accuracy in diagnostics. However, centralized laboratory tests are limited; they require relatively time-consuming processes, complicated equipment operations and trained personnel. Moreover, long wait times at hospitals and slow turnaround time for test results increase patients' feelings of unease, anxiety and fear before a final diagnosis is made.

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The diagnostic platforms of centralized laboratories are not widely applicable in developing countries, because such areas generally lack laboratory infrastructure, equipment and trained personnel, as well as access to a reliable electrical supply and clean water (McNerney, 2015; Kumar et al., 2015; Mabey et al., 2004; Pai et al., 2012; Mao and Huang, 2012). Many people in developing countries die from diseases that can be controlled or cured in developed countries. The top deadly diseases in the developing world are infectious ones, such as HIV/AIDS, malaria, tuberculosis and measles. These infectious diseases represent the greatest burden to developing countries (Yager et al., 2006; Mao and Huang, 2012). More than one billion people suffer from these diseases, all of which can be prevented and treated with timely diagnosis and early intervention (www.gatesfoundation.org, 2015).

Recent developments in point-of-care (POC) diagnostics have the potential to overcome the challenges facing both developed and developing countries (Luppa et al., 2011; Chin et al., 2012; John and Price, 2014; Ghafar-Zadeh, 2015; Weaver et al., 2014; Desai et al., 2011; McPartlin and O'Kennedy, 2014; Huckle, 2015; Abel, 2015; Jung et al., 2015; Chan et al., 2013; Song et al., 2012). POC testing can provide in-vitro diagnostics and immediately actionable healthcare information at accident sites, in doctors' offices, and in ambulances (Jung et al., 2015). POC tests can also, potentially, allow patients to self-test and self-manage care at their homes, which is especially useful for stigmatized conditions, such as sexually transmitted diseases and HIV/AIDS (Pai et al., 2012).

In direct contrast to laboratory-based models, which require benchtop laboratory facilities and complex procedures, POC testing offers a more decentralized diagnostic analysis that provides several additional benefits: portability and automation, as well as a capacity to offer diagnostic results in a shorter timeframe at reduced cost. Many useful POC products and testing tools are already on the market and have improved public health care. Such devices include POC tools for blood glucose testing, pregnancy testing, blood gas and electrolytes analysis, urine testing, bacteria screening, and forensic medicine, all of which enable continuous monitoring of patients' physiological information and reductions in the delay of therapeutic interventions. These benefits suggest that POC diagnostic testing can be even more useful in developing countries, where resources are limited and access to quality medical care is a challenge. Even in resource-limited settings, POC tests can be readily managed with minimal laboratory and handling by non-trained personnel. POC diagnostics therefore offer a powerful and promising emerging healthcare approach that is appropriate both in developed and developing countries.

A recent advance in molecular biology and bioMEMS (Temiz et al., 2015; Turner, 2013), has greatly enhanced the analytical performance of POC diagnostics, and as a result, numerous new POC applications have been proposed (Sackmann et al., 2014; Rackus et al., 2015). These advances are reflected in an increasing number of scientific publications, patents and commercial products that demonstrate high sensitivity, selectivity and reliability, as well as fast, accurate, cost-effective and user-friendly assays. However, several key challenges remain and must be addressed to realize a truly stand-alone POC diagnostic platform that does not rely on a competent laboratory service. The challenges involve developing quality assessment, system integration, and data management solutions. Above all, power autonomy must be considered for POC diagnostic tools, since POC testing performance depends significantly on power availability. POC device development has, however, tended to overlook the importance of power supplies even though they are necessary for moving/mixing/heating liquid, transducing/reading/tramsmitting signals, and analysing/managing data. If POC tools are to be of use in resource-limited regions, self-sustainable and stand-alone POC testing must be achievable because the electrical supply is often sporadic, and/or not widely accessible. In these areas, even powering POC devices with standard batteries can be problematic, as they represent a high cost and an environmental issue.

In this overview, we will review and discuss recent techniques for powering POC devices by their applications, and provide the reviewer's perspective on strategic power techniques for future POC diagnostics.

2. Power requirements and techniques for POC applications

Ideal POC devices can work independently and self-sustainably even in challenging field conditions, and are largely comprised of three functional components (Lee and Lee, 2013; Gencoglu and Minerick, 2014; Gubala et al., 2012): (i) fluid manipulation to transport, mix, separate, and control the analyte liquid, (ii) multi-step chemical processes to amplify a single copy of analyte molecules, perform cell lysis or carry out immunoassays, and (iii) molecular recognition and detection to sensitively identify and diagnose disease. Each component requires a different level of power consumption.

Normally, (i) fluid manipulation can be controlled by many microfluidic components, such as a micropump, microvalve, micromixer, and microseparator, each of which allow for autonomous, controllable, and on-demand fluidic manipulation (Nge et al., 2013). Those microfluidic components have been developed in the form of active or passive actuation techniques (Sin et al., 2014; Choi et al., 2011; Oh and Ahn, 2006; Nguyen et al., 2002). Active components require significant external energy to repeatedly apply external forces. Various actuation principles can be applied to exert mechanical or non-mechanical forces in those active components; effective methods include magnetic, electric, piezoelectric, thermal, electrochemical, phase change, and rheological actuation. More details on each component can be found in recent review articles (Oh and Ahn, 2006; Shaegh et al., 2015; Elizabeth et al., 2009; Melin and Quake, 2007; Nguyen et al., 2002; Zeng et al., 2009; Abhari et al., 2012). One mechanical movement (e.g. close or open the valve) demands power at the tens of mW to several W level, while non-mechanical actuation requires slightly less power consumption (Oh and Ahn, 2006). Some active components require a high voltage (~150 V) or current (~1A) to realize a few μm in mechanical deflection (Oh and Ahn, 2006). Several minutes of continuous operation for POC diagnostics will, therefore, require tens of W in power consumption; this can only be stably powered by domestic electric power, which is only available in developed countries. Passive microfluidic components are more preferable for ideal stand-alone POC diagnostics, because no external energy is required. Nonetheless, more stable and steady external forces must be generated.

The second functional component for ideal POC devices involves (ii) multi-step chemical processes (Sin et al., 2014). Chemical processing is necessary to enable sample preparation and increase the sensitivity/selectivity of the POC diagnostics. The type or number of processes will depend upon the applications. For example, DNA POC testing requires cell lysis and a polymerase chain reaction (PCR) (Sin et al., 2014; Gubala et al., 2012). The cell lysis is needed to release cellular contents (e.g. DNAs) and the PCR has been used to quantitatively reproduce DNA sequences for a high signal. After the analyte sample is collected, cell isolation and lysis followed by DNA extraction and amplification are performed. Many cell lysis techniques have been used, including optical, mechanical, acoustic, chemical, and electrical lysis methods (Brown and Audet, 2008; Escobedo et al., 2015). Mechanical and optical methods are not conducive to high throughput and low power POC diagnostics for two reasons: it is difficult to accurately position suspension cells for reproducible lysis, and relatively higher power consumption is required. Chemical lysis depends upon interactions with the lysis chemical, and thus is a relatively slow technique. Electrical and acoustic lysis are more preferable for the portable device platforms. Although electric field strength for the cell lysis depends on cell size and shape, electric voltage (0.2–1.5 V) should be applied over the length of a tens of μm cell to rupture its lipid bilayer. Recently, acoustic cell lysis using audio sources has been demonstrated with 107 mW power (Buser et al., 2015). Researchers performed cell lysis utilizing a portable audio device coupled with a simple and inexpensive electromagnetic