LionsGate TECHNOLOGIES

SOFTWARE-DEFINED MEDICAL DEVICES

A Technology White Paper

"The lack of available vital signs measurements is a significant limitation in global healthcare today."
- Dr. Mark Ansermino, Associate Professor, Department of Anesthesia, University of British Columbia, and Chief Medical Officer, LionsGate Technologies

OVERVIEW

Software-defined medical devices[1] offer an opportunity to address the growing burden of healthcare and access inequities worldwide, through ultra low-cost design.

Utilizing a proprietary analog AC-coupled bridging framework called ***Kenek Core™***, a wide range of inexpensive medical sensors can be connected to mobile devices through the universal audio port. Vital signs monitors implemented in software can measure blood pressure, body temperature, blood oxygenation, blood glucose levels, heart rate, respiration rate, and cardiac rhythm. By reducing the external hardware to a bare minimum and using the only port that is uniformly available across all mobile devices, a software-defined approach brings the design cost of vital signs monitors down to a fraction of current levels and makes them easily accessible to healthcare workers and consumers.

FIGURE 1
The mobile evolution of vital signs monitors (pulse oximeter example) from purpose-built handheld hardware, to compact smartphone-connected units, to software-defined medical devices. The only dedicated hardware in the ***Kenek Edge*** mobile pulse oximeter (right) is a low-cost finger sensor powered by the mobile device – the rest is a software app running on the smartphone or tablet.

GLOBAL DISEASE BURDEN

Healthcare faces severe challenges globally. In the developing world, infectious diseases and a lack of diagnostic tools result in a horrifying disease burden – millions die each year needlessly, many of them children. Elsewhere, chronic illnesses such as hypertension, asthma, cardiovascular diseases, and diabetes impact the quality of life for billions of people, costing billions of dollars each year, and killing millions annually.

>> **1.2 billion people with hypertension**
13% of all deaths due to cardiovascular disease

>> **1.0 billion people with chronic respiratory illnesses[2]**
180,000 deaths annually

>> **371 million people with diabetes**
4.8 million deaths annually

>> **2.5 million deaths annually from pneumonia in children under the age of 5**

Healthcare solutions for both the developing and developed world exist, but are often out of reach. These solutions are often limited, too expensive, or located too far from the individuals who need diagnosis and treatment. The most essential capability is to measure the vital signs of the body. The tools needed include pulse oximeters that measure blood oxygen levels and pulse rates, blood pressure monitors, thermometers, spirometers that measure lung function, ECG monitors, and glucometers for the measurement of blood sugar.

A critical first step toward addressing this global disease burden is to make vital signs monitoring tools easy to use, highly affordable, and universally available - *for everyone, everywhere.*

[1] Implementing a medical device in software on a general-purpose computing platform connected to a simplified hardware sensor.
[2] Chronic obstructive pulmonary disease (COPD), asthma, cystic fibrosis.

A SOFTWARE-DEFINED MEDICAL DEVICE SOLUTION

A key opportunity in addressing these healthcare challenges is to leverage the ubiquitous presence of mobile devices, such as smartphones and tablets. These general-purpose computing platforms enable ***virtualization*** of a wide range of vital signs monitors as software applications interfacing with inexpensive medical sensors.

Most medical-quality monitors are purpose-built, standalone hardware tools that are costly to make, difficult to update, and not always convenient to use. Vital signs monitors have five major components that are typically implemented in hardware:

- **>> A power source.**
- **>> A sensor, with communications interfaces, that detects the body state.**
- **>> A signal processor that translates the sensor signals into digital data.**
- **>> An analysis engine running on a microprocessor that derives specific measurements.**
- **>> A user interface that presents the data, measurements, and diagnostic output.**

Smartphones, tablets, and PCs enable a re-definition of standard medical devices - the software-defined medical device. By moving four of these five components onto a general-purpose computing platform, the software-defined medical device reduces cost and leverages the innate advantages of existing mobile devices.

The additional hardware required for a software-defined vital signs monitor is minimal - a connector, some cable, and a low-cost sensor. A software application drives and reads the sensors connected to the mobile device to generate vital signs measurements. The mobile device provides the user interface, processing, storage, connectivity, and power.

ENABLING SENSORS ON MOBILE DEVICES

For smartphones to support software-defined medical devices, they must be connected to the appropriate sensors to detect the body's vital signs. There are two primary means to connect a sensor – via wireless, such as Bluetooth, or tethered by a cable to one of the physical ports.

The widely promoted wireless option for connecting peripherals is Bluetooth. It is broadly used for personal area networks to connect devices together at short range. Other wireless standards exist that provide similar functionality including Ant, Zigbee, and UWB[3]. WiFi and 3G/4G cellular may also be used where greater distances are involved.

Wireless connectivity presents a number of challenges to the software-defined medical device approach. First, a sensor equipped with a radio must have its own power source. Second, it requires that the sensor include a microprocessor with a communications protocol stack, increasing its cost and complexity. Third, despite improvements like Bluetooth LE, wireless tends to be implementation-dependent and does not always work as seamlessly as it must to meet mobile consumer expectations for convenience and ease-of-use.

Most mobile devices have one or more physical ports. They include the audio (headphone) port, a proprietary docking port or USB[4] port, or sometimes a microSD[5] slot. Except for the 3.5mm audio jack, none of the other ports are common across mobile devices - there is significant variation between devices. Even the increasingly common micro-USB port is often missing.

The universal audio TRRS[6] port, common to almost all mobile devices, offers three data channels for communications – two channels of audio output and a microphone input. The audio systems behind the port are also relatively uniform with common performance characteristics typical of use for music or voice communications.

[3] Ultra-wideband – short-range, very low-power communications using large portions of the radio spectrum.
[4] Universal Serial Bus - an industry standard that defines cables, connectors, and protocols.
[5] A small form-factor format of the Secure Digital (SD) standard used for access to memory cards.
[6] Tip-ring-ring-sleeve (TRRS) connector provides stereo audio output and mono microphone input.

KENEK CORE

The ***Kenek Core*** audio sensor system enables standard medical sensors to be connected directly to mobile devices through the mobile device audio port. It implements analog-to-digital AC-coupling that allows software on the mobile device to drive the sensor directly and then receive response data back through the audio system. There are four distinct aspects to the ***Kenek Core*** system:

- **Hardware modifications to standard medical sensors** - 3.5mm 4-conductor TRRS audio jack and a few inexpensive electronic components.
- **A native software layer - the Real-time Audio Controller** - in the mobile operating system that accesses the sensor through the audio system using standard system calls.
- **The core signal processor software** that encodes the AC driver signal and decodes the response signal to generate a digital data stream.
- **An API** through which apps access data for analysis to generate vital signs measurements.

Application software (app) running on the mobile device accesses and controls the medical sensor using a set of simple commands through the API[7]. The ***Kenek Core*** software drives the sensor and decodes its data signal for the app. Together the audio sensor and app constitute a simple, scalable, affordable app-device[8] that performs as well or better than expensive hardware medical devices.

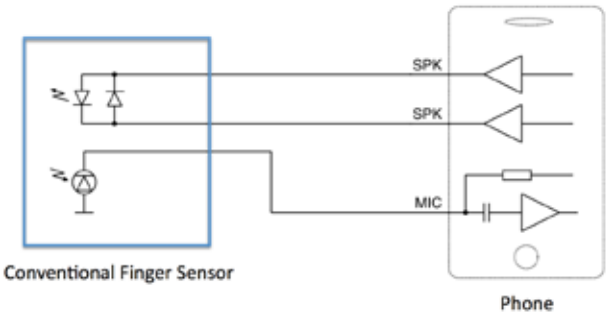

FIGURE 2
Simplified circuit showing a pulse oximeter sensor connected to the audio port of a smartphone.

FIGURE 3
The ***Kenek Edge*** mobile pulse oximeter including simple medical sensor connectivity and displayed oxygen saturation and pulse rate.

The proprietary ***Kenek Core*** software-defined medical device approach provides the following value:

Dramatically Reduces Costs

- **Minimal hardware.**
- **Uses standard sensors.**
- **Leverages mobile device.**

Design Simplicity

- **No microprocessor, stack, storage, batteries.**
- **No configuration required.**
- **Familiar mobile interface.**

Universality

- **Works with most mobile devices, also laptops and PCs.**
- **Utilizes ubiquitous 3.5mm audio jack.**
- **Adapts easily for use via USB port as well.**

User Experience

- **Eliminates need for batteries, external devices.**
- **Eliminates connectivity issues with Bluetooth.**
- **Uses connectors common for all mobile devices.**

A wide range of medical sensors can be implemented including LEDs and photo-detectors for pulse oximetry, pressure sensors for blood pressure and spirometry, strain sensors and accelerometers for motion detection, and differential voltage detectors for ECG and EEG. Some types of sensors like breath alcohol detectors require more power or voltage than mobile device audio systems provide. Some mobile devices are equipped with very low power or noisy audio systems that are not adequate to properly drive some sensors. ***Kenek Core***'s unique software approach ensures that accuracy and range of operation meets or exceeds that of traditional hardware medical devices.

[7] Application Programming Interface for integration with software applications.
[8] An app-device is composed of software running on a general-purpose computer and a hardware sensor.

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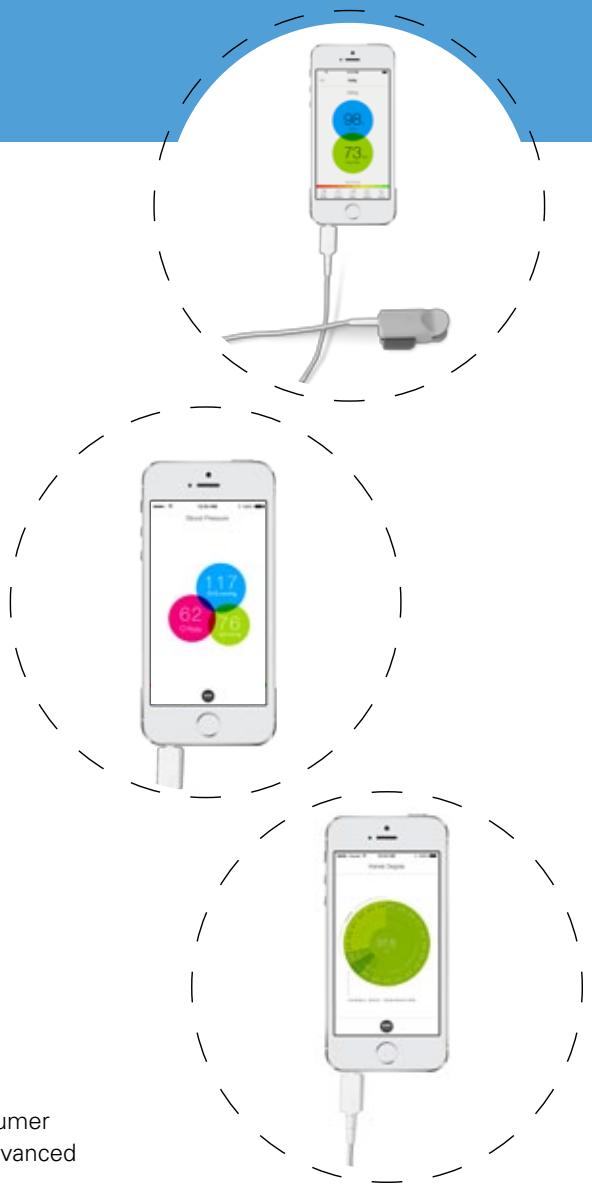

For example, the ***Kenek Edge*** app-device is a pulse oximeter composed of software on an Apple smartphone or tablet that utilizes the ***Kenek Core*** system and a finger sensor connected by a cable to the audio jack. It controls the audio signal sent to the LEDs in the sensor to provide optimal response for correct blood oxygen and pulse rate measurements across the required range of tissue transmission and perfusion. The ***Kenek Edge*** app is available in Canada and the US on the iTunes Store for all Apple devices running iOS 7 or later.

VITAL SIGNS MONITOR APPLICATIONS

Several vital signs monitors have been developed using the ***Kenek Core*** technology. These include a blood pressure monitor, a pulse oximeter, and a thermometer. Other vital signs monitoring applications have been identified or designed include a blood glucometer, spirometer, and ECG.

Mobile Oximetry

The ***Kenek Edge*** and ***Kenek O2™*** pulse oximeters use low-cost finger sensors designed to provide rapid and accurate readings of blood oxygen saturation (SpO_2) and pulse rate.

Mobile Blood Pressure Monitor

The ***Kenek BP™*** mobile blood pressure monitor is based on oscillometric detection of the blood circulation through a pressure sensor connector to an inflated arm cuff. It produces measurements of systolic and diastolic blood pressures and heart rate automatically from the sensor data.

Mobile Thermometer

The ***Kenek Degree™*** mobile thermometer utilizes thermocouples similar to consumer digital thermometers. It produces accurate measurements in seconds using an advanced predictive algorithm typically only available on expensive digital thermometers.

SUMMARY

The ***Kenek Core*** audio sensor system represents a critical advance in the development of low-cost, universally accessible sensors for vital signs monitoring. This advance allows the functionality of purpose-built hardware monitors to be virtualized into software-defined medical devices. With the unprecedented growth and penetration of mobile devices, the ***Kenek Core*** approach makes it possible to design clinical-quality vital signs monitors that:

- **Leverage the benefits of mobile devices - ease-of-use, connectivity, long battery life, and CPUs.**
- **Cost only a fraction of traditional vital signs monitors.**
- **Work on a wide range of mobile devices through a standard port.**
- **Ensure access to medical diagnostic and monitoring capabilities for everyone, everywhere.**

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