Alcohol content measuring system based on interstitial fluid extraction and surface acoustic wave (SAW) sensors.

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ABSTRACT

COGNA has developed an alcohol content measuring device that analyzes alcohol content in interstitial fluid. Interstitial fluid is the fluid between cells of the human body. It uses surface acoustic wave (SAW) sensors as the sensing devices and wireless communication to a cell phone, typically a smart phone. COGNA's device is unobtrusive, appealing to the wearer, and takes the form of a small, thin, flexible patch (about 2 x 3 inches) in contact with the human body. The gold standard in measuring alcohol content is analyzing a blood sample. Although accurate, this method is slow (more than a few minutes) and requires pricking a finger or other body part of a person. Many people object to this. Another current method utilizes analyzing the breath of people (using a so called breathalyzer). This method is not very accurate. It depends on the actual chemical environment of the mouth. Attempts have been made to analyze sweat or sweat vapor of people for alcohol content. Although interesting, this method has shortcomings. It is not accurate enough and not all people sweat.

Keywords**:** surface acoustic wave sensors, interstitial fluid, alcohol content.

SURFACE ACOUSTIC WAVE (SAW) SENSORS

Surface acoustic wave (SAW) sensors are a class of microelectromechanical systems (MEMS) which rely on the modulation of surface acoustic waves to sense a physical phenomenon. The sensor transduces an input electrical signal into a mechanical wave which, unlike an electrical signal, can be easily influenced by physical phenomena. The device then transduces this wave back into an electrical signal. Changes in amplitude, phase, frequency, or time-delay between the input and output electrical signals can be used to measure the presence of the desired phenomenon.There are essentially two types of SAW sensors: A 2 port (4 terminal) device and a one port (2 terminal) device. For wireless applications a one port (2 terminal device) is more feasible and COGNA's alcohol content measuring device is based on one port SAW sensors. A one port SAW sensor is typically operated at the resonant frequency, determined by the dimensions of the interdigitated transducer (IDT) and the reflectors. The frequency encoded in the returned electromagnetic signal is influenced by the properties of the chemically active layer. Frequencies are easy to measure. The deviation from the resonant frequency is a measure of the alcohol content (after some signal processing). SAW sensors are used ubiquitously as strain/stress/torque sensors. For the application as alcohol content measuring devices the SAW sensors are modified as chemical sensors by depositing and patterning thin layers, sensitive to alcohol, in between the interdigitated transducers (IDTs), acting as input and output, and the reflectors of the SAW sensor as shown In Figure 1. The sensor antenna is connected to the input/output terminals of the SAW sensor. A cross section is shown in Figure 2.

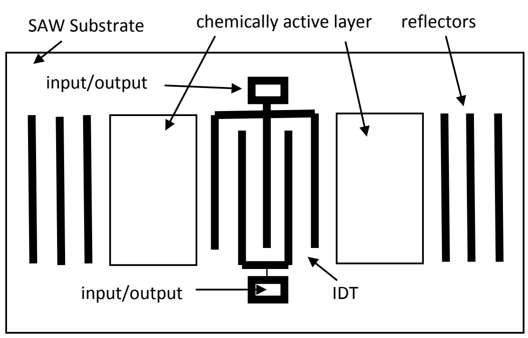

Figure 1 Chemical SAW sensor

SAW sensors are passive devices, that means they do not require a power supply such as a battery. They are powered by the electromagnetic field emanating from the antenna of a Reader system (Data logger). SAW sensors can be either wired or wireless. In the current application we use a wireless version. The advantages of a wireless SAW sensor are obvious. No physical connection of the sensors to a Reader system (a smart phone in our case) is needed. Since SAW sensors are passive, the distance from the Reader antenna to the sensor antenna has to be less than the reading distance of the sensor. Depending on operating frequency and other parameters this can be several meters. In the application as an alcohol content measurement system this should not be an issue since the distance between the sensor and the smart phone is about one meter.

SAW devices are inherently accurate. The sensor antenna, connected to the IDT of the sensor, receives an electromagnetic signal from the smart phone. The frequency of this signal is typically in the MHz range or higher. Since the SAW sensor is placed on a piezoelectric substrate (for example quartz), an acoustic wave with a frequency in the kHz range is launched by the IDT in both directions (left and right in Fig.1). This wave is contained close to the surface of the SAW sensor.

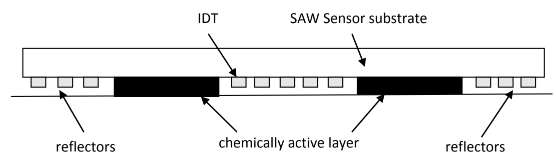

Figure 2. Cross Section of chemical SAW sensor

It diminishes exponentially away from the surface. The wave velocity and the phase strongly depend on the surface property of the SAW sensor. The surface acoustic wave is reflected by the reflectors and is received again by the IDT. It is reconverted into an electromagnetic wave that is received by the smart phone antenna. This signal contains the surface velocity and the phase of the SAW sensor. By placing layers sensitive to alcohol between the IDT and the reflectors, the SAW sensor is converted into a chemical SAW sensor and the surface velocity and the phase are influenced by the alcohol content. In other words, the electromagnetic signal received by the smart phone contains the concentration of alcohol. In our case the alcohol sensitive layer is a layer of dye-Chitosan. There is some signal processing required to extract the alcohol concentration. That means that some proprietary software has to be loaded into the smart phone. The processing capability of a smart phone is sufficient for this signal processing.

SAW sensors are inherently accurate. Small changes in the surface condition can be detected. In our case, small changes of alcohol concentration can be measured. We assume that an alcohol concentration of about 0.01% has to be detected with a legal limit of about 0.05% (in some states). This is well within the accuracy of a chemical SAW sensor.

SAW sensors are also inherently reliable and stable. The same results are obtained by repeated measurements. Since SAW devices are passive, i.e. no batteries that have to be replaced are needed, they essentially live forever.

SAW sensors are inexpensive since they are manufactured using integrated circuit (IC) principles with at most three photolithography steps. Turning a SAW sensor into a chemical SAW sensor requires one additional photolithography step to pattern the chemically sensitive layer. IC fabrication typically requires more than 20 photolithography steps. A chemical SAW sensor costs less than 50 cents in volume.

SAW sensors are sensitive to temperature. It is normally not easy to distinguish a temperature from a chemical effect in the SAW signal. However, the human body is a good thermostat and in the present application, temperature effects should not be an issue. But if they are, Albido Corporation (in which one of the authors has an equity stake) owns a patent separating the effects of temperature and physical parameters. COGNA holds a nonexclusive license to this patent.

COGNA'S PRODUCT

Fig. 3 and Fig.4 show the patch that is applied to the human body and is part of COGNA's alcohol content measuring product. As mentioned before the alcohol content is determined in interstitial fluid. A human has about half its body mass as interstitial fluid. Interstitial fluid is typically excreted as urine. However, the current device is not analyzing urine. We are extracting interstitial fluid transdermally, i.e. through the skin. This is a

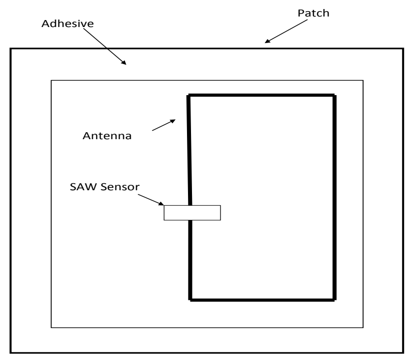

Fig. 3 Patch of COGNA's alcohol detection device based on SAW principles.

challenge. Normally transdermal transport it done in the reverse direction. There are products on the market that administer drugs from a patch through the skin to the body. For example Testost CYP, a drug against hypogonadism, is typically injected but can also be administered as a gel. Administering a drug as a gel on a patch attached to the skin is done whenever an oral drug cannot withstand the stomach acid or injection is not an option. The transdermal transport, in this case, happens through diffusion, from the patch, through the skin to the blood stream. In the current product we are extracting interstitial fluid. Diffusion is possible if the concentration of the substance in question is greater in the body than in the SAW sensor, but this is typically not the case. The interstitial transport is increased with the osmotic pressure. Osmosis is a process where the solvent (normally water, but interstitial fluid in our case) flows from a lower concentration to a higher concentration through a semipermeable membrane (human skin in our case) and thus equalizes the concentration on both sides of the membrane. In our case (determining the alcohol concentration in interstitial fluid) we have to provide a solvent with higher concentration in the chemically active layer of the SAW sensors than in the interstitial fluid. In our case, we use the pH.

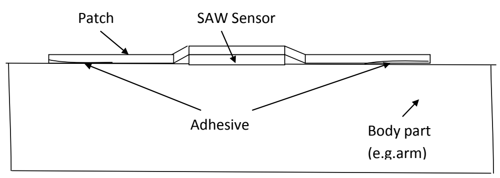

Fig.4 Cross Section of patch of COGNA's alcohol detection device based on SAW principles.

The pH of interstitial fluid is around 7. We are pre-conditioning the chemically active layer of the SAW sensor with a solvent with a low pH (e.g. around 3), lower than the pH of interstitial fluid. Because of the osmotic pressure, interstitial fluid will then flow from the body through the skin to the sensors.

Chemical SAW sensors have the big advantage that they can operate with a very small volume of liquid (in the microliter (µl) range) which is about one drop. That means, we do not have to extract large amounts of interstitial fluid.

Figure 5 shows COGNA's product. The sensor antenna is part of the patch (see Fig. 3) and the Reader antenna is the antenna of the smart phone. The smart phone has to perform some signal processing. As mentioned before, this is well within the scope of a smart phone. An app which contains the signal processing software is loaded onto the phone.

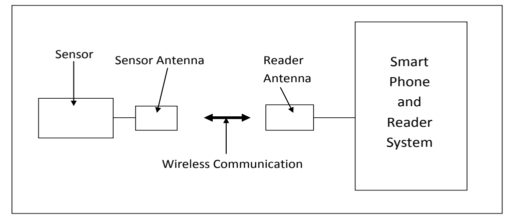

Fig.5 COGNA's alcohol detection device based on SAW principles.

COGNAs product can be used by individuals, law enforcement personnel, and other parties. The app loaded onto the smart phone could also extend to other functions such as disabling the operation of a vehicle if the alcohol concentration is larger than a given threshold.

COGNA has applied for a US patent covering the main aspects of the product. Of course there is competition. The main competition is from devices that measure alcohol level in blood. However this is cumbersome, slow and expensive. Law enforcement likes breathalyzers. This is probably because they are user friendly, reasonably fast and inexpensive. However, as mentioned before, they are not very accurate. This is an issue since alcohol content in blood of more than 0.08% is illegal in most states. The biggest market, in our opinion, is with individuals. Since everybody nowadays has a cell phone it is no big deal to load COGNA's proprietary software onto the phone as an app. The patches themselves are inexpensive. An individual can attach a patch to his arm or other body part and knows whether he/she is below the legal limit before driving a motor vehicle. He/she does not have to prick a finger, does not have to sweat and does not have to breath into a tube.