Printed Electronics for Medical Devices

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Abstract
As is the case with many other markets where faster, highly capable technologies have resulted in more intelligent processes and products, the medical device sector is also undergoing a "smart" transformation. This has driven the development of medical devices that provide greater access to in-home care and monitoring and faster results for medical professionals, with the overarching benefit of better patient outcomes. Devices applied to the human body that continuously sense and report vital signs in real-time, moisture sensing systems that aid in patient health and comfort optimization, and skin-applied patches with timed drug measurement and release are all smart healthcare realities today. Sensor technologies that bridge the gap between standard, rigid assemblies and more flexible user interfaces are pushing the envelope toward smaller and more convenient form factors, making smart healthcare devices a mainstream reality. This paper will share details about multiple medical sensing applications and the advanced materials and processes used to assemble them for optimal functionality.

Introduction
The printed electronics industry has existed for decades but is receiving renewed attention and focus as an enabler of miniaturization, the ability to accommodate flexible assemblies with improved form factors, and cost efficiency. In the decades since its emergence, printed electronics has progressed from the production of printed circuit boards, through to the now commonplace use of membrane switch, RFID, photovoltaic, and electroluminescent technologies. The average consumer unknowingly utilizes printed electronics on a daily basis, as many modern-day devices contain printed electronic elements. While several applications leverage the capability of printed electronics, the medical market – which has utilized printed electronics for several decades – is tapping into new electronic material capability for the development of smart medical devices. As patients request more convenience and cost efficiency, printed electronics is answering the call by facilitating the development of more stretchable, flexible, conformal and biodegradable electronics devices. An additional benefit is that by incorporating printed electronics, thinner and lighter devices can be manufactured -- including those in hybrid constructions which incorporate traditional rigid chips and components, conventional integrated circuits, light emitting diodes, and more. These evolved hybrid devices are capable of performing functions which are not yet achievable with printed electronics alone.

Within the medical sector, there is a growing need for real-time monitoring and a push for its existence in outpatient environments. Simultaneously, patients and medical professionals want smaller, less expensive products. In order to meet these ambitious objectives, manufacturers are turning to solutions that can deliver high-volume, cost-efficient manufacturing and printed electronics technology is central to this effort. Printed electronics techniques offer a viable solution for the convergence of miniaturization and lower costs, while also enabling the reduction of manufacturing expense by as much as 40% and allowing for smaller design builds. [1] This is critically important as manufacturing of smaller, wearable medical devices expands dramatically with significant growth projected over the next four years. According to a report, the wearable medical devices market is expected to reach $14.41 billion by 2022, up from $6.22 billion in 2017 [2,3].

Cost Efficiency Enabled by High Throughput Printing Methods
There are a number of different printing methods utilized for applications in the medical field. For the bulk of the applications incorporating printed electronics, the three primary materials deposition technologies are flatbed (screen/stencil), flexographic and rotogravure printing.

Flatbed screen printing is the oldest printing method and is thought to have originated in China close to 800 years ago. The oldest screens were made from silk, hence the reference to "silk screening". Today's screens consist of a woven mesh constructed using polyester or stainless steel which is stretched over a metal frame. Ink is placed onto the screen and a rubber squeegee moves across the screen, pushing the ink through the screen and leaving an image on the substrate. There are many parameters that dictate the coating thickness applied by flatbed printing, with the primary determinants being screen mesh size, emulsion thickness, and squeegee hardness and sharpness. These parameters can be tailored to each specific application by following some general guidelines. While screen printing plays an important role in most sectors of the printed electronics, it is not a prevalent manufacturing process due to volume constraints and the impact that has on cost. Instead, flexographic or rotogravure printing is the preferred print method for most medical applications utilizing printed electronics.

Flexographic (flexo) printing is a continuous process that is typically made up of different stations, each with the capability to print and cure a layer of ink. Typical flexo lines for graphic printing have four stations made up of a print head and a drying or curing system such as forced air, UV or IR. There are two types of flexo presses: sheet fed, which is used primarily for printing on cardboard, and web fed. Web fed is the preferred press type for the printed electronics industry, as the continuous roll to roll processing inherent with newer flexo machines can process upwards of 2000 feet per minute. With printed electronics, however, the deposit thicknesses and drying capabilities needed for current functional inks dictate a slightly slower print speed, which averages closer to 100 feet per minute. An example of a typical flexo press can be seen in Figure 1.

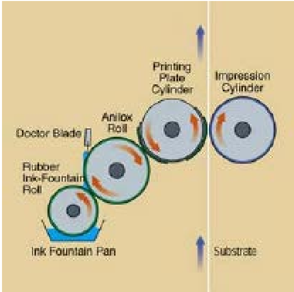

Figure 1: A typical flexographic press design

Rotogravure is currently capable of providing the fastest speeds for printed electronics techniques. With proper drying, rotogravure can reach speeds capable of processing 3000 feet per minute. Due to the heavier volumes of ink that can be deposited, rotogravure is often used for high-end magazines where color and photographic type quality is important. Because of its speed and precision, rotogravure also lends itself well to the processing of low-cost, high-volume medical device parts such as EKG and tens pads, as well as other electronic applications such as RFID devices. Rotogravure is a web-fed process with multiple print and curing stations much like flexo, but on a larger scale, an example of this can be seen in Figure 2.

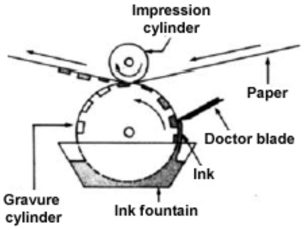

Figure 2: A typical rotogravure type system

Ink Material Solutions

The printed electronics industry has developed many different types of inks to suit the needs of various applications. While some are market/application-specific, there are inks that are cross-functional and can be used for a variety of applications including those in the medical sector. Inks are used to print sensors for a variety of medical applications (Figure 3) and are among the most cost-effective materials for medical device production.

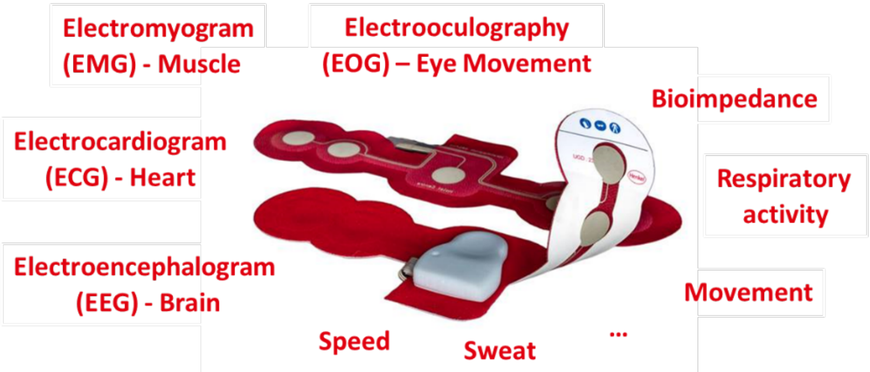

Figure 3: Biomedical sensors can monitor a variety of bodily functions and transmit the data for analysis

The formulations used for printing sensors and resistors vary widely in resistance values and compositions and must be capable of meeting a number of key performance properties required for the production of medical sensors, including: high conductivity, fine line resolution, fast drying time, substrate compatibility and flexibility, to name a few. The ink characteristics are tailored by the selection of the formula components, such as the fillers, resins, carriers, and any other solid/liquid additives. Ink functionality is larger driven by the type of fillers selected, such as silver, silver chloride, carbon, phosphors, insulating materials, etc. and the filler's physical characteristics, such as particle shape and size distribution, density, surface area, etc. The filler type determines the ink's functional use, such as conductivity, isolation, resistors, capacitors, electrodes, antennas, light emitting, RF absorption/reflection. Rheological characteristics and printability of the ink are influenced by the selection of carriers and resins, and any additives; the previously mentioned filler properties also play a large role in the rheological properties of the ink. Carrier and resin types are selected based on compatibility, and in addition to rheology, also determine ink characteristics such as adhesion, cohesion, flexibility, abrasion resistance, chemical resistance, environmental stability. The printed electronic inks are designed to serve a variety of functionalities while being able to perform on many different substrates and function properly under varying environmental conditions. Printed electronic inks can be designed using water-based, UV-curable and solvent-based systems, which incorporate different resin and carrier systems, with the conductive pigments of silver and carbon being the primary carriers of electrical and thermal conductivity.

Silver is the most electrically and thermally conductive material of all the metals, which has the unique ability to remain conductive even after oxidation has occurred. In fact, the oxides that are produced on silver are as conductive as the silver itself. This makes silver an ideal material for use where fine inner particle contact is important. Inks developed for high conductivity are employed throughout the printed electronics market and are used as the primary circuitry carrying the electrical current to all components on a given board or flexible part. Generally speaking, most companies desire the highest conductivity printed lines achievable at a reasonable cost. A highly conductive (<10mOhm/sq/mil) ink is desirable from a cost saving perspective, but also because less ink is required to achieve the desired electrical properties and thinner layers enable lower height profiles for miniaturized devices. This can allow for a more uniform/level application of additional ink layers, such as dielectrics, and assist with part uniformity in stacked or layer builds, such as EKG sensors that can include silver, Ag/AgCl, and dielectric layers in the design. In addition to reducing trace profile, highly conductive inks that have the ability for fine line resolution can help to reduce the overall size of the final part by allowing for consolidation of the print area by allowing for smaller trace dimensions, some examples of fine line capabilities can be seen in Figure 4.

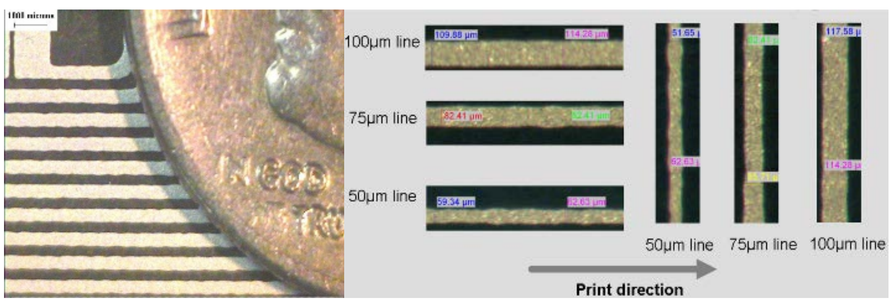

Figure 4: Typical conductive traces for fine line printing capabilities

As medical devices continue to expand in application and functionality, the variety of substrates utilized is also on the rise. Thus, the compatibility of inks with multiple substrates becomes critical. Additionally, inks need to offer in-use flexibility without any degradation of conductivity or adhesion, which is essential for most typical medical sensor applications. Figures 5 and 6 highlight the most recent advancements in ink conductivity and flexibility technology. Typically, inks that have a high level of flexibility have a lower conductivity due to formulation requirements but, as seen in Figures 5 and 6, inks have been developed that have a higher conductivity while also maintaining or improving on flexibility performance.

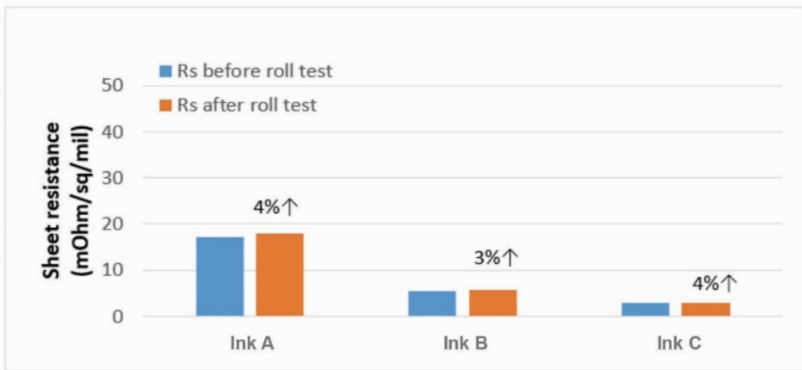

Figure 5: Sheet resistance of silver conductive inks before and after roll test

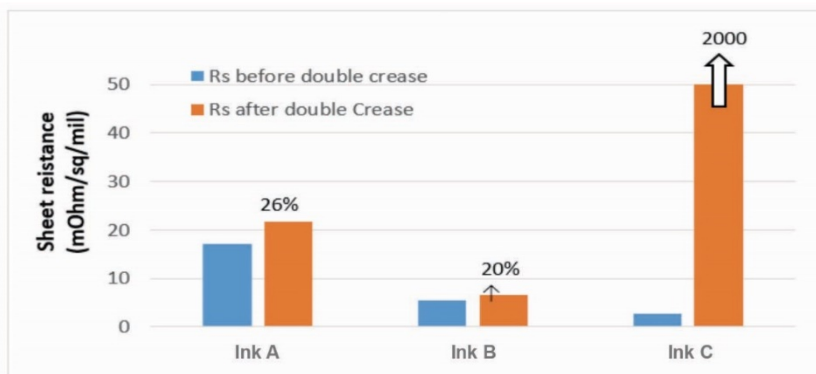

Figure 6: Sheet resistance before and after double crease test

In these figures we can see the performance of several inks in two standard flexibility tests. The first test is the roll test, in this test conductive tracks are printed and cured on a flexible substrate, such as PET, and the tracks/substrate are then rolled around 4mm cylinder with the ink facing inside & with the ink facing outside. All three inks performed well in roll testing exhibiting 3-4% change in resistance. For the crease test conductive tracks are printed and cured on a flexible substrate, such as PET, and the tracks/substrate are then creased and then that crease is rolled over with 1.8kg roller with the ink facing inside and with the ink facing outside. Inks A and B exhibited good flexibility performance, the performance of Ink C in the crease testing can be attributed to the semi-sintered state it achieves during curing. The main differentiator between these inks is the level of conductivity of inks B & C. The improved conductivity and ability to maintain various levels of flexibility exhibited by these conductive inks allows for the design of medical devices that can more readily conform to the curved shapes of the human body, such as the flexible sensor patch in Figure 7.

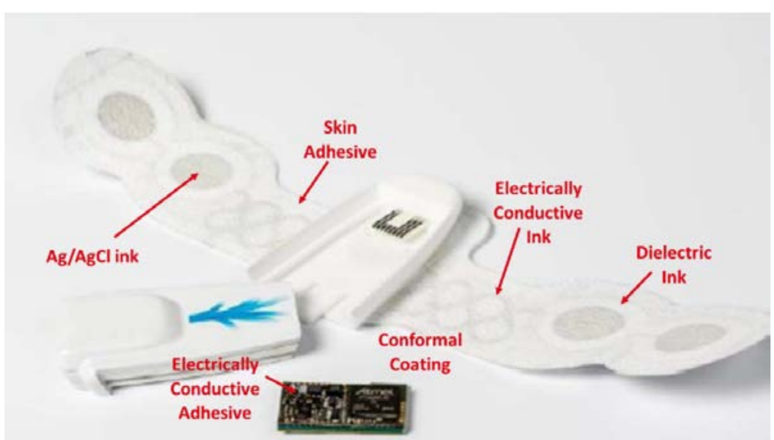

Figure 7: Typical sensor pad on flexible substrate representing a multiple layer build

Dielectric inks play an important role in the structure of printed circuitry because they provide environmental protection to the printed conductive trace, inhibit shorting and make it possible for multi-layered printing to take place, as see in Figure 8. This allows for higher density circuitry designs. Dielectrics are also used to help minimize silver migration, which is especially important where there is current draw and moisture present in a printed circuit. Dielectric formulations are made for thermal cure and UV cure systems, with the vast majority of systems being the latter. The 100% solids formulations and crosslinking properties make UV systems the preferred chemistry choice for most applications, as they allow avoidance of thermal cure cycles that may damage temperature-sensitive components and substrates used in medical applications. The ability for fast processing speed combined with the chemical and environmental resistance benefits these inks deliver makes them ideal for use in low-cost medical devices.

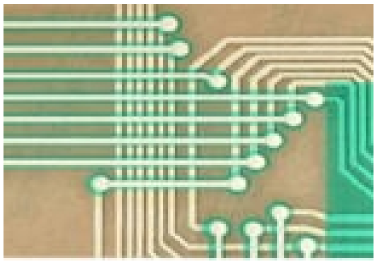

Figure 8: An example of a multi-layered print with dielectric crossover

Carbon inks (or carbon graphite blends) are also used across the entire field of printed electronics. Carbons are typically three orders of magnitude more resistive than silver but generally are less costly. Carbon systems are incorporated in applications where resistance is a requirement and used as a component of the functional part. Some of these applications include printed resistors, heaters, potentiometers, force sensing and moisture sensing applications. The most common examples of carbon ink use in medical devices is within applications that require force sensing and moisture sensing. Resistance ranges for adjustable force sensing, or FSR (Force sensing resistor), inks can be seen in Figure 9.

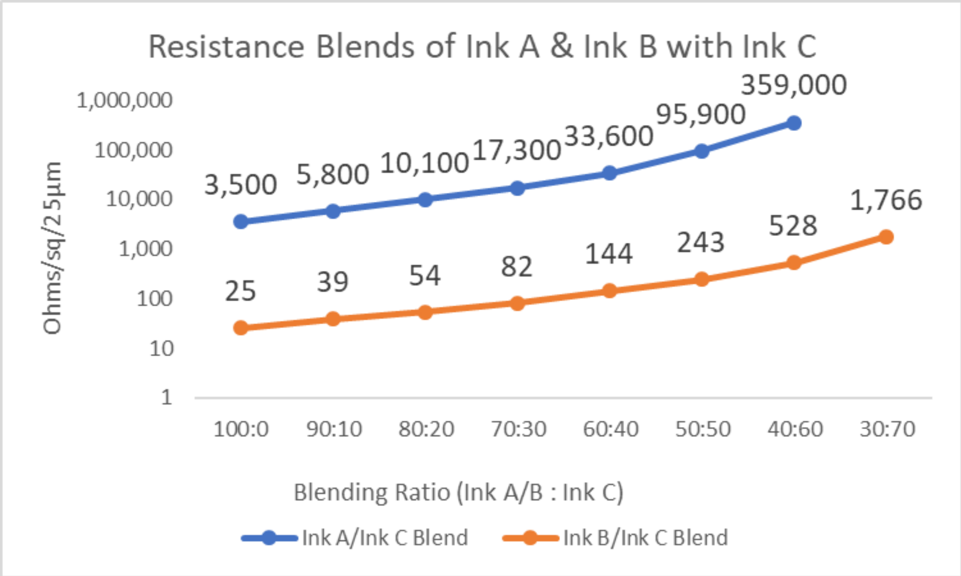

Figure 9: Sheet resistance ranges of blended FSR ink systems

FSR devices exhibit a decrease in resistance with increase in force applied to the surface of the sensor, this effect is reversible with the removal of the said force. The wide range of resistances available by blending these inks creates the capability of designing a wide range of devices capable of different initial resistance and sensitivity profiles which remain stable in use, an example of these ranges is shown in Figure 10.

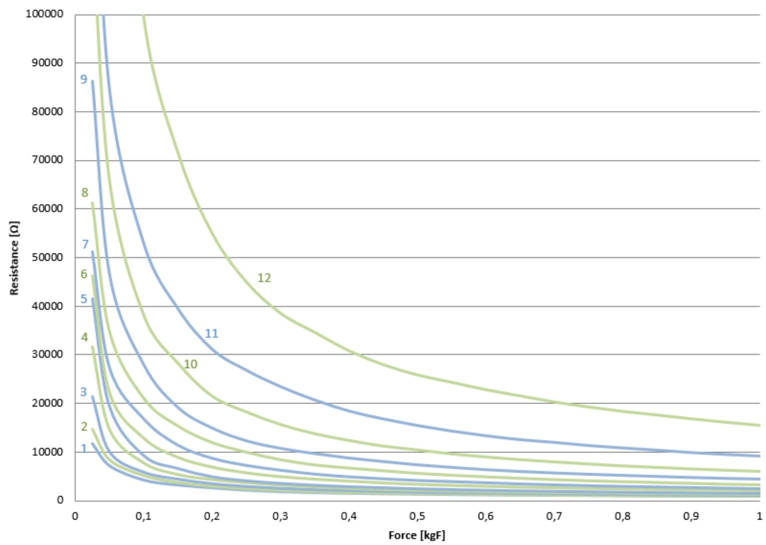

Figure 10: Examples of force sensitive profiles, resistance as a function of force, for various material blends

Force sensors have a variety of end uses that range from detection of wheelchair occupancy to recognition of pressure points. New developments in sensor design not only allow for occupancy detection on a yes/no basis, but also position- and force-specific applications, such as fall prevention detection. In this type of application, sensors could be used to alert staff if a patient is attempting to get out the bed or has/has not shifted their weight appropriately in a bed.

Moisture sensors that either short or register an impedance change with the introduction of moisture are being widely used in hospital, nursing care and home care settings for the monitoring of personal hygiene. Additionally, this type of sensor has been utilized in the design of smart diapers for both children and adults, which can be seen in Figure 11.

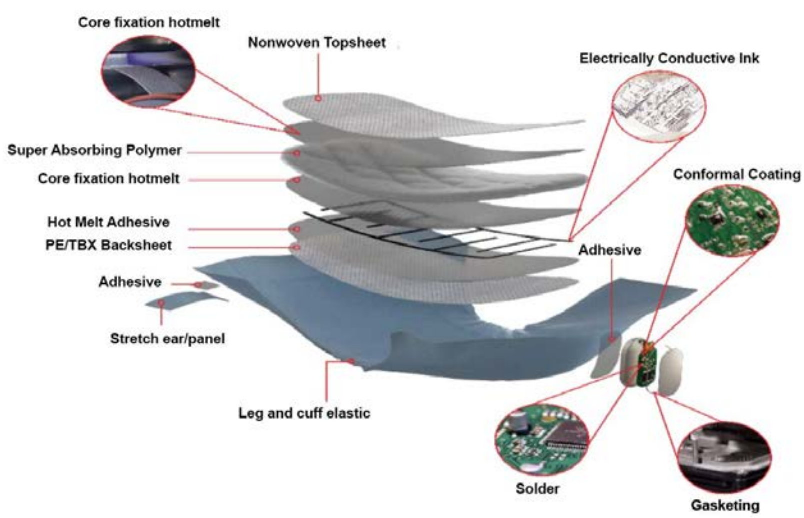

Figure 11: Example of a smart diaper designed for moisture sensing and monitoring

Silver/silver chloride inks systems are primarily used for medical applications, and specifically for sensors, ECG, EKG, EEG, TENS and defibrillator electrodes. These electrodes measure biopotential while acting as a transducer that converts ionic currents from the body surface into electrical signals and are a critical component in current biomedical electrode systems. Functionality is achieved through the combination of silver inks and conductive gels, with the inks being printed directly onto the ECG pad. An example smart pad can be seen in Figure 12.

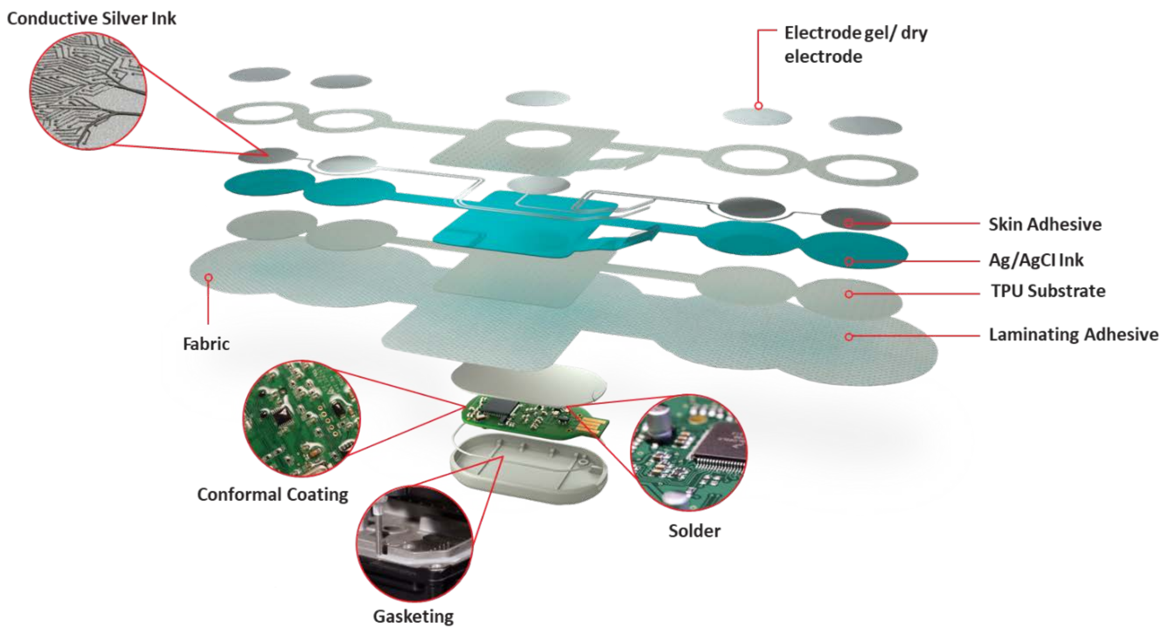

Figure 112: Example of a smart patch build utilizing Ag and AgCl inks

The silver/silver chloride pad and electrolyte gel are combined and, when placed against the skin, form a conductive salt bridge that detects electrical pulses generated by a specialized tissue, organ or cell system. [4,5] Another use for silver/silver chloride inks is for drug delivery systems, also known as Iontophoresis. Iontophoresis is a process where electrical current delivers medicine or other chemicals through the skin. This process operates under the same principle as an ECG pad where silver/silver chloride inks combine with a conductive gel. In the case of Iontophoresis, the gel is loaded with the drug to be delivered, a current is applied, and the system ionizes the skin to initiate drug delivery. By changing the amount of current applied, the drug delivery rate can be increased or decreased.

Positive Temperature Coefficient **(**PTC) inks are growing in the medical field for applications that require various levels of heating with targeted maximum temperatures. Functionality is achieved based on the ink's reaction to the current that passes through it. When current is introduced, PTC inks begin to heat and become less conductive as the temperature increases. When the inks reach a pre-determined, application-specific temperature target, they go through a phase change at which point the ink resistance increases greatly, as demonstrated in Figure 13. This prohibits electricity from passing through the circuit and effectively shuts down the unit until the ink cools below its phase change temperature. When the ink temperature drops low enough, current is reintroduced. A representation of this can be seen in Figure 14. Currently, this ink technology is most widely incorporated into automotive applications but is also being utilized for temperature control of intravenous (IV) fluids for medical applications. Heating of the IV fluids, which are generally stored at room temperature prior to infusion, can not only improve patient comfort, but can also potentially minimize or eliminate complications associated with hypothermia due to the intake of low temperature IV fluids. Through proper ink selection and design build, PTC inks allow for fast, efficient, and controllable heating, while also removing the need for external temperature controllers and regulators. This not only helps to drive the overall simplification of design build, but also reduces the number of components needed to build the functional part, thereby lowering cost, simplifying production and resulting in more compact and flexible devices.

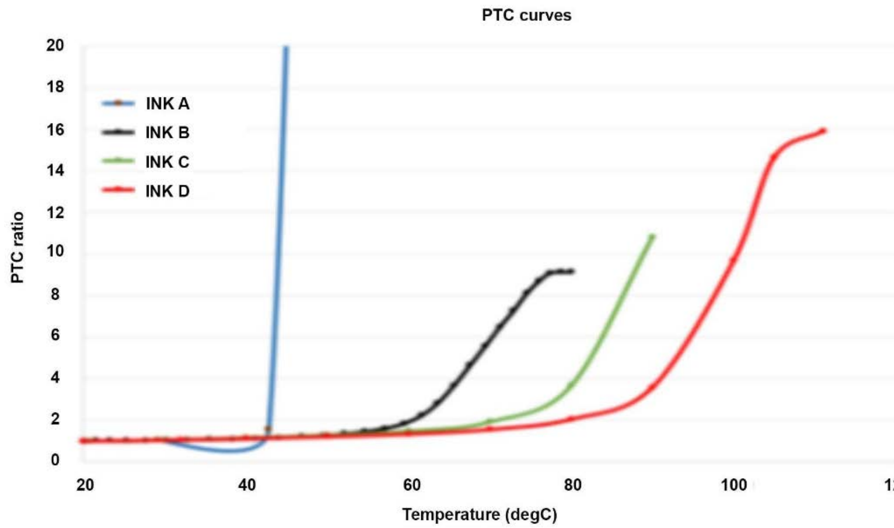

Figure 12: Plot of PTC ink maximum temperature curves

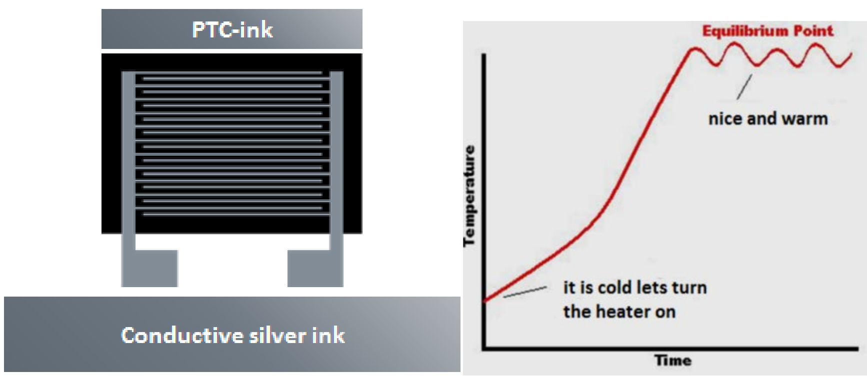

Figure 14: Representation of a typical PTC heater over time

Summary

While printed electronic techniques have been utilized in the medical field for decades, recent developments of smart medical devices have seen printed electronics and sensor technologies become key enablers of modern health care advancements. The ability to manufacture devices in high volume that enable expedited detection and diagnosis, improve patient comfort, facilitate self-monitoring for better outcomes and lower overall costs to manufacturers, physicians, medical facilities and patients is all made possible by printed electronics. The functionality delivered and throughput rates available through the additive process of printing electronics will no doubt ensure its viability for the foreseeable future. Increasing product diversity and the need for form factor modifications will drive further growth of printed electronics in the medical device industry, as new methods of technology adaptation and integration continue to be developed.

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