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Technical Paper

Wearable Sensors from the "Skin-Side" Out

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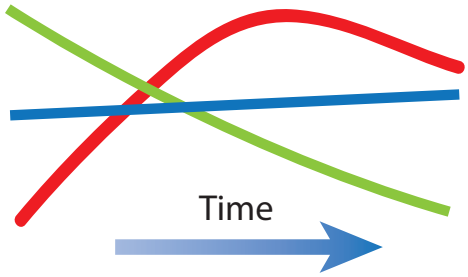
One of the hottest topics at the 2014 Consumer Electronics Show in Las Vegas was wearable sensors. These devices power everything from smartphone apps that allow patient information to be entered at bedside to watches that not only tell time but monitor your heartbeat. Many of them automatically download their information to databases, update charts and might even contact your doctor or emergency medical personnel if you're outside certain parameters. Who needs a tricorder when you have a watch that tracks your health and is smaller and easier to transport?

However, several weeks after the show there was news of a recall due to skin reactions caused by one of the wristband sensors. This type of negative press can be used to re-focus the attention of designers and engineers of these high tech inventions on remembering who they're dealing with – humans who haven't really changed much over the years. If the device will contact skin, everyone must remember not to treat the human skin interface as an incidental and, often, last step before market. Multiple issues including direct and indirect contact with skin, quality of the components, possible interactions between the materials, ergonomic requirements and target patient population characteristics should all be taken into consideration early in the design process of these revolutionary devices.

Materials selected for the device need to be of high quality – food grade[1] or "medical" grade components are smart and safe choices. The FDA requires registered medical devices to have safety testing of the entire finished device but careful selection of quality materials at the beginning can often reduce the risk of unwelcome results late in the process resulting in redesign and missed timelines. It is also good design practice to take common skin allergens and irritants into consideration when selecting components, especially for the outer layers of the sensor. Natural rubber-based (often referred to as "latex") compounds, nickel in metal alloys, plasticizers and more can be avoided if sensitizer awareness is part of the early concept work. In addition to affecting the skin interface, these choices can affect other materials used in the device construction. Certain elastomeric polymers (i.e. plasticized PVC) can interact with adhesives to make them non-functional; the same additives that make them flexible interact with most adhesives post-assembly causing them to fail. Silicone rubber makes a soft and pliant structure for device housings but may limit other material selection choices as the designer tries to bond the silicone rubber to other component layers of the device including the skin. Knowledge of these and other usability factors can help product designers and materials engineers select components that allow the skin in contact with the device to remain healthy.

Using quality materials may reduce some risks but understanding the true functional characteristics of skin is critical. All too often, we see specifications in which designers propose sensors or therapeutic delivery devices with expected attachment to skin of 2-4 weeks. These goals are extremely challenging when it has been shown that surface skin (epidermis) cells renew themselves constantly. Many areas of the skin stay "intact" for only 7-10 days before completely turning over.[2] Occluded sections may slough off even faster as the body tries to shed the perceived "irritation" and return moisture and oxygen transmission levels to normal.

Adhesion Level to Skin over Time

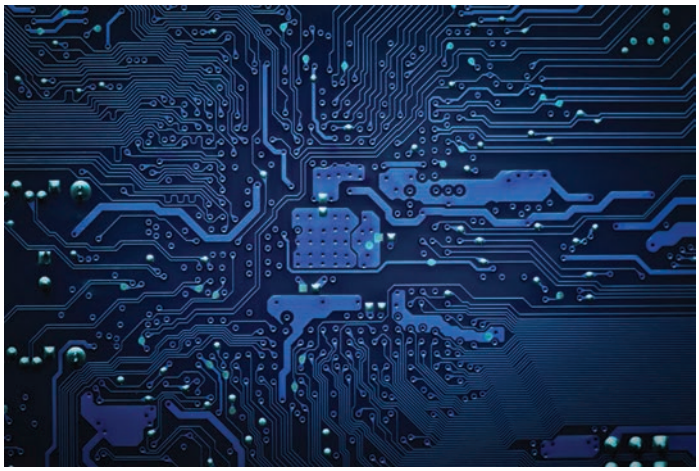


Having reference to how different types of adhesives work with skin can help reduce the development time of prototypes and avoid late-stage design hurdles. There are different adhesive families such as Acrylates/Acrylics, Synthetic Rubbers, Silicones, etc. that may or may not provide the same initial adhesion to the selected substrate. All have good applications in the medical and retail device marketplace depending on the age range (geriatric/neonates versus healthy adult), device placement (thin skin/eye areas versus feet), device size and length of wear needed (one hour, one day or one week). Adhesion levels can be greatly affected by dwell time on the substrate. Devices intended for short term wear (a few minutes to several hours) benefit from choosing adhesives that have good initial stick but don’t build adhesion to skin quickly, which minimizes discomfort during removal. A slow build of adhesion level typically happens with many acrylic-based adhesives – lower adhesion initially but increasing then stabilizing over time allowing for longer term attachment of around seven days depending on the individual and their activities. Many synthetic rubber-based adhesives have excellent “quick stick” properties to low energy surfaces[3] like skin but can be mechanically irritating if removed soon after attachment. These same adhesives are very good for devices requiring 24 hours to three days wear since the adhesion to most skin types tends to decline over time resulting in less irritation.

For industrial designers, adhesives can be evaluated using test panels of their own materials and/or with standardized substrates. This is not possible with human skin. Many efforts have been made to find or develop a good substitute for in-vivo human skin testing. Studies range from various plastics such as low density polyethylene to high tech lab-grown skin.[4] Some will reproduce initial adhesion and are often used during early stages of medical device development. You can still use adhesion to stainless steel or low surface energy plastics (low density polyethylene for example) to get an idea of very short term or initial adhesion to human skin. These substrates can work as guides - for the first hour or two of adhesion.

Another design point to consider in the early stages is the overall thickness of the finished device, specifically those intended to be adhered to the skin. High profile (a.k.a. thick) devices tend to catch on clothing if worn on the arm, leg or high on the chest. Devices that are higher profile can often be worn on the front of the abdomen above the beltline or incorporated into a wristband. Clothing interference can also be reduced by using an overlay of a thin low-friction fabric tape or conformable film tape. Designs using printed or other thin, flexible circuitry during development may help the device attain a lower profile and also increase comfort during weartime by being more conformable.

Knowing the end-user target population for the device can also affect component choices.[5] Attachment to skin is often a bell-shaped curve with the majority of potential users grouped in the center and smaller percentages at both ends of the curve. On the low end there will be people with skin that never seems to become irritated or may not allow adhesives to hold securely for very long. The opposite end of the curve are those who seem to be sensitive to many materials and/or those who have skin that easily reddens or otherwise reacts to any adhesives. Dry, fragile skin is prone to this type of reaction and only the gentlest adhesives should be considered or adhesives should possibly be combined with a skin “primer” or protective preparation applied before attaching the device. For adhesive attachment, simple soap and water cleansing of the skin works very well to remove surface contaminants and, after thorough drying, leave little or no residue as another possible source of irritation.



Each sensor design is unique and can enable a wonderful expansion of healthcare from a clinical setting into the home and workplace. Amazing potential exists for better performance at lower overall cost to maintain and possibly improve quality of life - not only for people who are already healthy but also to allow more freedom and portability for those currently “tethered” to bulky equipment. In their work, designers and engineers need to remember they are designing these unique devices for a wide range of people, not steel-skinned machines, and select materials to interface with the human factor. It is always easier to design a good interface from the start than have to retrofit a solution late in the process.

References

[1] Per FDA 21CFR175 for plastics. Visit http://www.fda.gov/. The FDA does not define what constitutes “medical” grade for devices at this time. 3M Medical Specialties tests adhesive components according to ISO:10993-5 & -10 for direct contact with intact skin and manufactures under medical device level cGMP conditions.

[2] Fore, J.; A Review of Skin and the Effects of Aging on Skin Structure and Function, *Ostomy Wound Management*; 2006, 52 (9), p. 24.

[3] A standardized measurement - in dynes/area – often used in the printing industry with lower dyne levels equated to surfaces that are more difficult to print.

[4] Cantor, Adam S., Peel Adhesion Using An Artificial Skin As A Predictor Of Adhesion To Human Skin, 3M, *American Association of Pharmaceutical Scientists Annual Meeting*; New Orleans; November 14-18, 1999.

[5] McNichol et al; Medical Adhesives and Patient Safety: State of the Science: Consensus Statements for the Assessment, Prevention, and Treatment of Adhesive-related Skin Injuries; *J Wound Ostomy Continence Nursing*. 2013;40(4):365-379.

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