SKIN-WORN WEARABL

A Pronat Medical employee performs a quality inspection on a wearable device. (Credit: Pronat Medical)

E DEVICES:

Tomorrow's Vision, Today's Realities

In the fast-expanding world of wearable medical devices, an entrepreneurial spirit is driving dreams of a digital health future into reality. Collaboration on material selection and testing early in the development cycle can help smooth the road to innovation.

Imagine, if you will, a remote Chinese village. A small cottage sits far from the road surrounded by rice fields. Inside, an elderly woman and her husband enjoy a simple dinner, chatting about their next trip to the city to visit their son's family and new grandchild. … A few hundred miles away, that very same son and his wife are preparing dinner in their high-rise apartment, discussing some issues that came up at work and his concerns about his mother's recent fall. "We're lucky Dad was home," he says. "But if it happens again, at least now we have some peace of mind." A quick glance at his smart phone assures him his mother has been in stable health today.

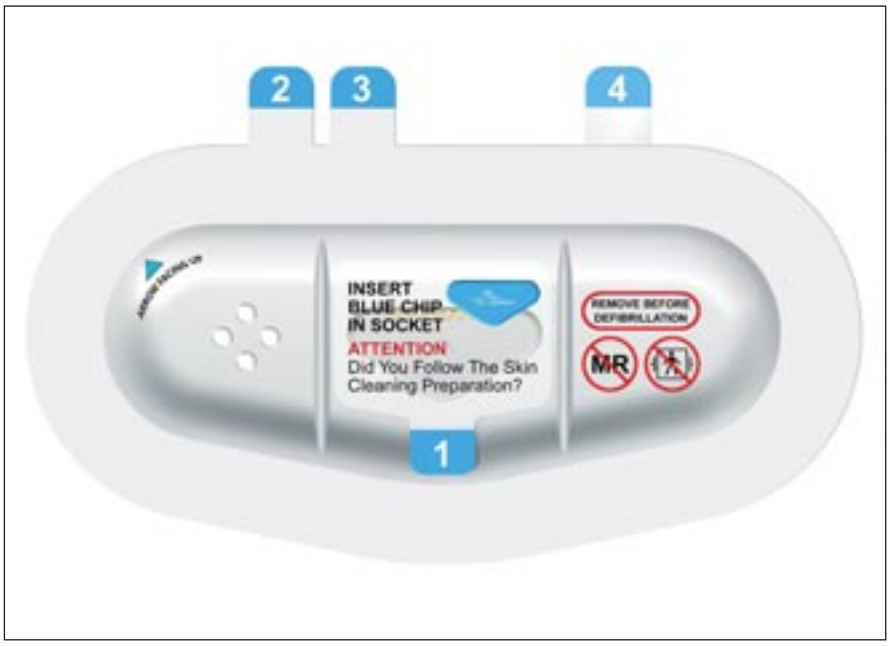
An app receives continuous streams of data from a small patch his mother has worn since she tumbled in the garden last month and struggled to stand back up. Now the app's digital health algorithms send him an alert if something is awry so that he can immediately get in touch with his parents' nearest neighbor and the village nurse practitioner. … In the room next door, a baby suddenly stirs, whimpers a bit, then falls back asleep. Again looking at his phone, the son, now also a concerned new father, sees that the child is running a low-grade fever. Thanks to a tiny monitoring device gently but surely adhered to the infant's tender skin for the past few days, the new parents don't have to disturb their son to check his temperature. "If it doesn't break by morning, I guess one of us will need to take him to the clinic," he says. "Yes," says his wife, "but why don't I schedule a quick WeChat televisit tonight with the on-call nurse to see if there's something more we can do?" With a sigh of relief and a good plan of action, they return to their meal preparations. …

This hypothetical family could be anywhere in the world. Their common concerns about relationships, wellness, illness, physical distance, time, and work are universal. Their core needs for connectivity, especially in matters of the heart and health, are shared by all.

Wearable medical device solutions to meet these needs are flowing swiftly into the market. Some of these wearable medical devices store the data on the patch throughout a prescribed wear period. Then the patient removes the patch and mails it to the medical device vendor for analysis. Other skin-fixation devices transmit signals via wireless networks, which connect the raw data feeds to sophisticated real-time monitoring software. Depending on the application and the monitored condition, healthcare providers and other caregivers may be alerted in the event of a medical problem, or they might view or analyze the information at regular intervals.

LifeWatch® Services, a company that develops remote patient diagnostics, recently received FDA and CE approval for its Mobile Cardiac Telemetry Patch. This product utilizes a comfortable, hydrocolloid skin adhesive to provide long-term skin fixation for its sophisticated ECG sensor with mobile signal processing. The patch detects cardiac rhythms and wirelessly transmits the ECG data in real time to LifeWatch for analysis. The special choice of hydrocolloid adhesives enables patients to continue normal activities, including showering, while wearing the patch for extended periods.

The possibilities, applications, and configurations for wearable medical devices are virtually limitless. In the disease prevention arena, cosmetics giant L'Oreal recently released its My UV Patch, which alerts users about how much ultraviolet sunray exposure they have received so that they know when to apply protection. Among wellness applications, Kenzen is gaining momentum with its body-worn patch that measures athletes' electrolyte levels in real time. In chronic disease management, researchers are working steadfastly on noninvasive ways to measure blood glucose levels with skin-worn monitors that analyze tiny droplets of sweat. In the future, these wearables may not only monitor diabetic patients but they may also deliver life-sustaining medication.



Designed for long-term skin fixation, the LifeWatch Mobile Cardiac Telemetry Patch detects cardiac rhythms and wirelessly transmits the ECG data in real time to LifeWatch for analysis. The industrial designer for the Lifewatch patch was www.trim-id.com. (Credit: LifeWatch Services Inc.)

During medical wearable device converting, Pronat Medical uses an integrated pick-and-place robot and laser line in its cleanroom. (Credit: Pronat Medical)

Wearables: An Expanding World of Opportunity

While projections vary quite a bit, there is consensus among some leading market researchers that the medical wearables category is steadily expanding. Market Data Forecast estimates the global market for wearable medical devices will reach $11.18 billion by 2020, growing at a compounded annual growth rate of over 19 percent.[1]

Market research firm Tractica expects worldwide shipments of body sensors to increase from 2.7 million units in 2015 to 68 million units by 2021. "Healthcare is expected to be one of the biggest drivers for body sensors, particularly connected wearable patches," the firm says.[2]

IDTechEx projects medical device wearables will reach $31.6 billion by 2026, with the potential to be a $100 billion business over a longer term (beyond a decade). Lengthy product

These rotary converting machines in Pronat Medical's cleanroom are used for mass production of wearable devices. (Credit: Pronat Medical)

development cycles for medical wearables are a factor that has capped growth at a relatively modest pace so far, the firm said in a 2016 webinar.[3]

Skin-Fixation Devices: Where Art and Science Merge

When it comes to wearable device product development, early decisions about material selection can make an enormous difference in launch timelines, performance, and ultimately, the patient experience. It's beneficial to work with a material supplier, converter, and industrial designer with strong understanding of anatomy, medical device quality standards, and the properties and characteristics of diverse material options.

During the initial stages of product development, there are big advantages to keeping an open mind and detailed dialog going between partners about device parameters, desired functionality, target price, size, and wear time. A device maker may have specific materials in mind, but a medical specialist converter may be able to recommend other options that will offer equal or better skin fixation, breathability, and conformability. The device end use will drive many of these decisions. For instance, device stability on the skin for very short wear times can be most important for patches used for some drug-delivery applications. In this case, fast, secure adhesion is more important than breathability.

For other end uses, such as cardiac monitors worn continuously over a two-week period, the ability to manage sweat and bodily fluids is a much greater priority. Without a highly breathable material, the patient may not be able to tolerate the device, which could lead to serious skin sensitivity and irritation problems. Working together with the device manufacturer, an experienced industrial designer, material manufacturer, and medical specialist converter can suggest both skin-contact and construction materials to manage varying levels of moisture — through allowing vapor transmission or moisture absorption.

There is both art and science involved in choosing the right materials, testing them, and integrating them into a fully functional wearable device. For example, the materials manufacturer, working through the specialist converter, will be able to provide biocompatibility reports and documentation for each material used in a skin-contact adhesive. These will include results for cytotoxicity, irritation, and sensitivity according to market standards (ISO 10993). The material data sheet will specify the adhesion strength and other key performance characteristics. These are critical scientific metrics.

However, there also is a need for a great deal of qualitative analysis. An experienced wearable device converter should be skilled in the art of wear-test experimentation. How long does a material truly adhere under a variety of conditions? Will it stay on the skin for a week with regularly showering? How will it handle intense movement and profuse perspiration from vigorous exercise? How does a patch feel on the skin over time? How do these factors vary depending on patch placement on different parts of the body? How easy is it to remove from the skin? The answers come from years of wear testing and trial runs — of putting oneself in the patient's skin, so to speak — to see how materials truly perform. And this can be more art than science.

Conclusion

Product development of wearable devices requires strong data to back up claims for biocompatibility, wear time, and moisture management. But it also benefits from the softer skills, such as a refined sense for which design elements will deliver the most effective performance along with aesthetic appeal and comfort. For without a good patient experience, a wearable device isn't likely to be worn as prescribed, if at all.

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