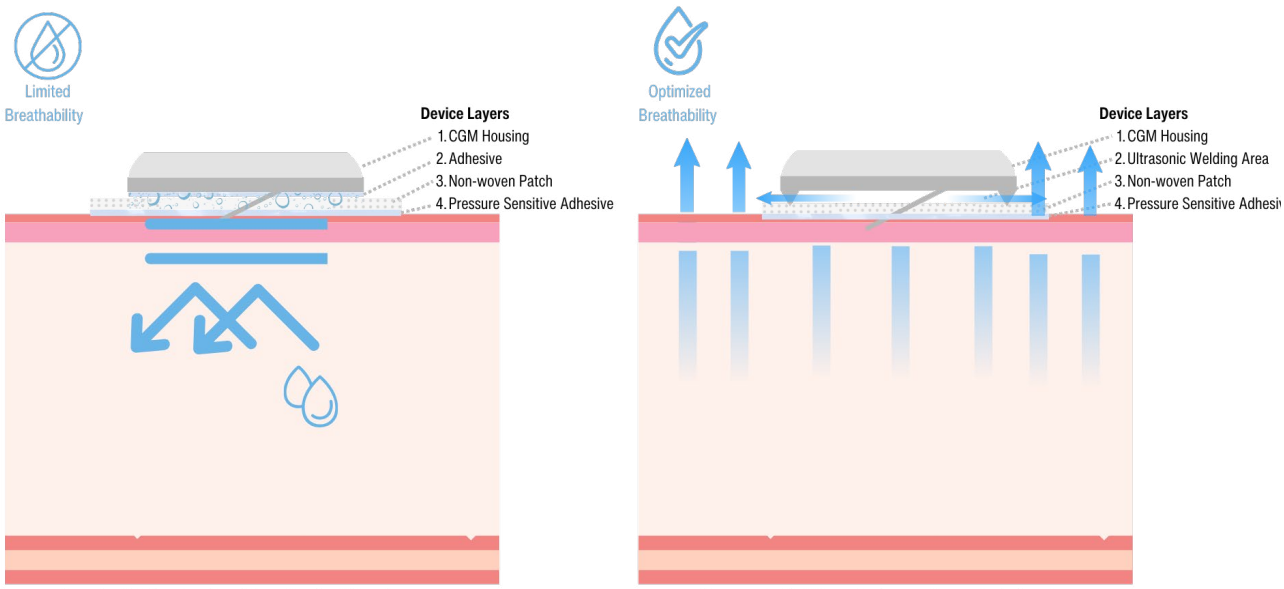
Herrmann Ultrasonics

Key Considerations for Designing Medical Wearables

Choosing the Right Design and Bonding Methods



Standard Adhesive Bonding - Limited Ventilation Adhesives create an airtight seal, preventing moisture vapor from escaping and increasing the risk of skin irritation.

Ultrasonic Welding - Enhanced Breathability for Improved MVTR Ultrasonic welding creates breathable bonds, reducing moisture buildup and promoting comfort.

Why MVTR (moisture vapor transmission rate) and selecting the best assembly method is important for your products success and patient experience.

One major reason people get contact dermatitis is due to increased humidity and occlusion. This problem is becoming more common as the wearing times of medical wearables are increasing. For example, infusion sets can be worn from three to seven days and CGM devices for up to 14 days.

To prevent skin damage from long wear times, humidity, and being covered, the Moisture Vapor Transmission Rate (MVTR) should already be taken into account during product development.

MVTR and Its Importance for Skin Compatibility

MVTR stands for Moisture Vapor Transmission Rate. It measures the rate at which moisture vapor passes through a material, typically expressed in grams per square meter per day (g/m²/day).

High MVTR values indicate good breathability. The rate for normal skin is 204 g/m2 per day.

This rate is affected by wearing medical wearables because they form a skin barrier making it difficult for moisture to pass through. Stronger adhesives or thicker adhesive coatings are often used to make products more durable for longer wear times. However, this creates extra stress on the skin and increases the risk of irritation.

Therefore, the most important goal for manufacturers is to improve skin compatibility by keeping MVTR as high as possible.

Considerations for Design

Creating a great design and selecting the right materials and bonding methods for both design and manufacturing requires a comprehensive approach.

Medical regulations, like those from the FDA, prioritize user needs. Specifically, understanding the patient's skin needs is crucial when designing products.

Understanding Critical Factors

An undesired skin barrier is created because the sensor or device needs to stick firmly and closely to the skin. The construction often begins with a skin adhesive with a non-woven backing, forming a skin adhesive patch. The sensor or device is then placed directly on top of this adhesive patch, which reduces the Moisture Vapor Transmission Rate (MVTR) of the medical wearable.

Even if the adhesive patch itself has a good MVTR, the device sitting on top further reduces or blocks the skin's ability to breath. Additionally, the sensor or device must be securely attached to the non-woven backing, which can be done through heat bonding or adhesive.

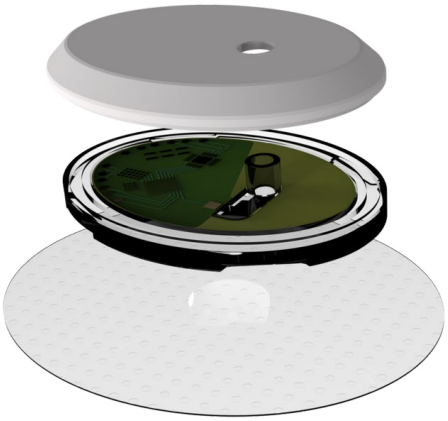
To prevent the sensor from peeling off prematurely, some manufacturers recommend using overpatches.

Overall, this setup creates an unwanted barrier, trapping moisture and heat, and contributing to a less-than-ideal environment for the skin.

Common Challenges When Designing a Medical Wearable for Improved MVTR and Wear Comfort

After selecting the right skin adhesive patch that provides good adhesion and high MVTR, the next challenge is to securely attach the device or sensor to the non-woven backing of the patch.

This step is crucial to ensure the device stays in place while maintaining comfort and breathability for the skin.



Big Challenges When Using Heat Sources for Sensor/Device Bonding

The non-woven backing is designed to be flexible, allowing it to adapt to different skin types and the curvy surface of the body. It should be soft or fluffy, ensuring good skin contact and wear comfort for the patient.

However, when heating is applied to bond the sensor housing to the non-woven backing, the soft structure of the non-woven material can be compromised, creating a stiff, rigid surface.

High temperatures applied from an external source (such as heated tools) to achieve bonding or melting can create microchannels in the material, which weakens the bond and compromises the adhesive structure.

This not only reduces the desired comfort but can also significantly affect the material's properties, as the melted backing no longer provides the intended flexibility. This issue is well known in industries such as hygiene and textiles (e.g. baby diapers, face masks, and underwear).

Ultrasonic welding has been the preferred bonding method in these industries for many years, as it avoids the high temperatures that causes these damaging effects.

Invisible but Noticeable Limitations Due to Heat

Excessive heat can damage the coating of the release liner, which is designed to peel off easily from the adhesive tape. While the damage is not visible, patients will notice it when they try to remove the release liner, as it may stick to the adhesive and leave behind residues on the skin patch.

This can prevent proper use of the device or sensor, or weakening the adhesion, leading to premature peeling and device failure. As a result, manufacturers may face faulty products, customer complaints, and high costs for replacements, as well as the risk of losing customers.

Another common method for bonding the device to the non-woven backing is using a "sensor mounting tape" or "reactive adhesive."

While this adds another layer of adhesion, it also creates an additional barrier that significantly reduces the Moisture Vapor Transmission Rate (MVTR). This limits the skin's ability to breathe and also prevents proper ventilation between the non-woven backing and the device housing.

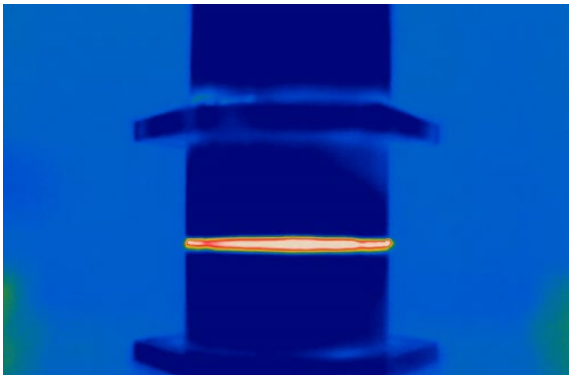
Over time, accumulated moisture or sweat can weaken the bond, further compromising the device's performance.

Adhesive-free Bonding with Ultrasonics

Adhesives – especially sensor adhesives – can pose risks, such as the presence of IBOA – a known allergen that can cause skin irritation.

Ultrasonic welding is a safe, non-chemical bonding method that applies energy only to the desired weld zone for a fraction of a second, generating limited internal heat. This process offers two key benefits for manufacturers:

- A high bond strength of the housing/device to the non-woven backing, with fewer contact points or areas of connection
- It allows for the design of ventilation gaps and drainage channels, improving airflow and reducing the risk of moisture buildup.



The infrared image shows: When welding with ultrasonics, high temperatures only occur within the previously defined joining zone.

By using ultrasonic welding, manufacturers can create a securely bonded device that prioritized patient safety without the need for adhesives.

Sustainable, Cost-Efficient Bonds

Eliminating the need for additional joining agents offers several benefits for manufacturers.

Firstly, the overall cost-efficiency of the process improves, as manufacturers no longer need to store, transport, or purchase expensive medical adhesives. The fast process cycles – without the need for surface preparation or finishing – allow manufacturers to significantly increase their Overall Equipment Efficiency (OEE).

Not only do manufacturers and their products benefit from eliminating adhesives and other chemicals in the joining process, but so does the environment. Without them, the entire process becomes considerably more sustainable, which helps companies meet their own or statutory sustainability targets.

As the medical products no longer contain any additional joining materials and can be recycled by type, they can be added to the circular economy again. This also optimizes the sustainability balance of the entire product lifecycle.

Conclusion

Designing medical wearables requires a comprehensive approach that carefully considers both patient comfort and the technical demands of prolonged wear. Ensuring a high MVTR and selecting the right bonding method are crucial to creating wearables that maintain a balanced skin environment, prevent irritation, and promote breathability.

Ultrasonic welding, as an adhesive-free bonding solution, not only enhances the durability and comfort of medical devices but also supports a more sustainable manufacturing process.

By minimizing additional adhesives, manufacturers can reduce material costs, improve process efficiency, and contribute positively to environmental goals. Overall, the future of medical wearables lies in balancing patient needs with innovative, eco-friendly design solutions that prioritize both health outcomes and sustainability.

Speak to us for a comprehensive consultation and let's design better devices for tomorrow.

Have questions? We are here for you!

Selina Kiefer and Team
Selina_kiefer@herrmannultrasonics.com
www.herrmannultrasonics.com