ORPYX
sensory insoles

Personalized plantar temperature monitoring for DFU risk reduction

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Executive summary

Problem

Current remote temperature monitoring (RTM) protocols use a standard 2.2°C plantar temperature asymmetry threshold to identify early signs of foot inflammation.

A standard threshold may not be appropriate for individuals with comorbidities that can confound plantar temperature monitoring.

Solution

To individualize the care plan, the Orpyx® Sensory Insole features a personal baseline temperature asymmetry algorithm.

Outcomes

Personalizing temperature monitoring to an individual's baseline helps to reduce burdensome false positive temperature warnings, as well as reduce the risk that new plantar temperature elevations are missed.

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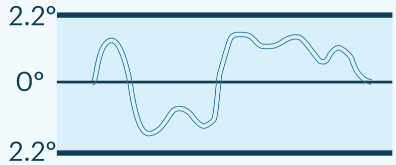
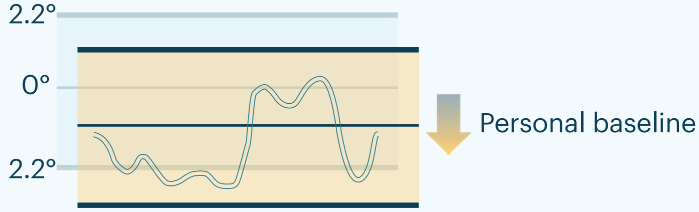
Key terms

Temperature asymmetry: Temperature differences between corresponding regions on the left and right of the foot.

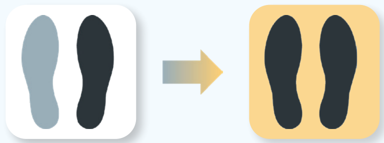
Standard asymmetry threshold: A fixed population threshold of 2.2°C plantar temperature asymmetry for two consecutive days.



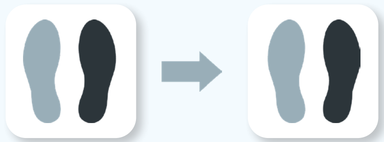
Personal asymmetry threshold: Personalized thresholds adjusted by an individual's baseline temperature asymmetry.



False negative risk: Temperature asymmetries that do not exceed the standard asymmetry threshold but do exceed an individual's baseline adjusted threshold.



False positive risk: Temperature asymmetries that exceed the standard asymmetry threshold but are within the baseline temperature asymmetry.



DFU: Diabetic foot ulcer.

Introduction

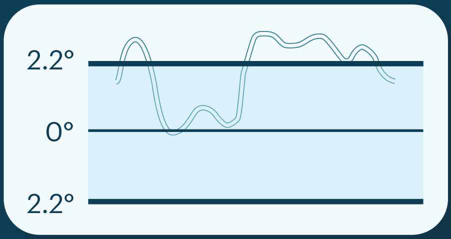
The Orpyx Sensory Insole System combines multimodal sensory insoles with patient-facing biofeedback and remote patient monitoring (RPM). This digital health solution provides an adjunct to standard of care that helps prevent the development of diabetic foot ulcers for individuals living with diabetes and peripheral neuropathy. A comprehensive suite of pressure, temperature and motion sensors are embedded into prefabricated or custom insoles, a convenient form factor that slips discretely into prescribed therapeutic footwear.

Clinical evidence has demonstrated the Orpyx technology is effective in significantly reducing diabetic foot ulcer recurrence and reducing the cost of care when used in conjunction with current standard of care.[1,2] The mechanism by which the Orpyx system supports DFU prevention is through enabling and reinforcing proven foot health management guidelines.[3,4]

The purpose of this white paper is to highlight the proprietary baseline temperature asymmetry algorithm from Orpyx. The algorithm, when used in conjunction with standard RPM protocols, can personalize care to the individual and optimize how and when plantar temperature trends of concern are escalated to the provider.

The state of temperature monitoring

Studies as early as 1986 have demonstrated the value of plantar temperature monitoring for the evaluation of the diabetic foot.[5] As of 2015, foot skin temperature monitoring to identify early signs of foot inflammation (for patients at moderate or high risk of foot ulceration) are included in the guidelines on the prevention and management of diabetic foot disease published by The International Working Group on the Diabetic Foot (IWGDF).[3] In 2022, a meta-analysis of five randomized controlled trials (RCTs) summarized that at-home foot temperature monitoring and reduction of ambulatory activity in response to areas of warmth reduces the risk of DFU.[6] Additionally, the Society for Vascular Surgery and the Wound Healing Society (WHS) both include plantar temperature monitoring in their diabetic foot health management and prevention recommendations.[7,8]



Foundational research studies informing temperature monitoring guidelines have typically utilized a fixed threshold for identifying plantar temperature data trends of concern: when temperature differences between corresponding regions on the left and right foot (i.e., temperature asymmetries) exceed a threshold of 2.2°C (4°F) for 2+ consecutive days, this is considered a hot spot of concern.[3,6,9,10]

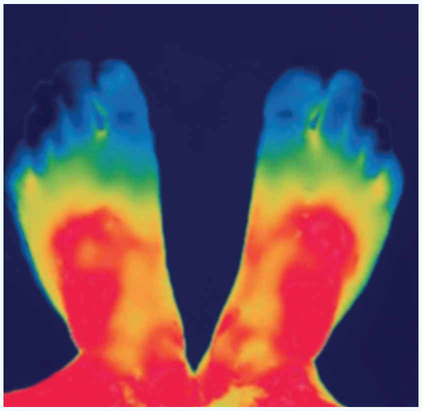
Current fixed threshold may not be appropriate for all users, as certain comorbidities and patient circumstances can present as baseline plantar temperature asymmetries.

To better support individuals with baseline temperature asymmetries, the Orpyx Sensory Insole system now includes a personal baseline temperature asymmetry algorithm. This development in plantar temperature monitoring advances industry standard protocols for plantar temperature monitoring in the diabetic foot by providing warning thresholds personalized to the individual.

Common comorbidities and patient circumstances

People living with diabetes can have numerous issues that manifest as limb temperature asymmetries independent of DFU formation. These comorbidities and patient circumstances can confound traditional temperature monitoring protocols and are an additional challenge for managing DFU risk.

Symmetric at baseline



Asymmetric at baseline

Peripheral arterial disease

20-50% of individuals with diabetes are also burdened by peripheral arterial disease (PAD).[11] Underlying asymmetries in limb perfusion may present as plantar temperature asymmetries. **In individuals with asymmetric vascular disease, established temperature monitoring for DFU risk may yield false positive risks in the warmer limb, and, more concerningly, false negative risks in the cooler limb.** Potentially informed by this challenge, some prior studies on the use of temperature monitoring as a self-assessment tool to prevent ulceration excluded individuals with PAD.[9,12]

Additional patient circumstances

Foot deformities, immunocompromise, lifestyle, environmental factors, insole geometry, offloading modifications, and assistive tools such as braces can all impact plantar temperature asymmetries. In some cases, baseline temperature asymmetries may be attributed to one or more of these patient circumstances, not inflammation.

Wound healing

34% of individuals with diabetes are likely to develop a DFU during their lifetime.[13] During wound healing, individuals with diabetes often suffer from prolonged inflammation.[14] **With half of recurrent ulcers developing on the opposite foot,[15] warming of the contralateral foot may be overlooked.** With wound healing times taking up to 3 months with standard RM protocols,[16] this is a critical period to ensure baseline temperature asymmetries are identified and accounted for.

Charcot arthropathy (Charcot foot)

Up to 10% of individuals with diabetes present with Charcot foot.[17] Plantar temperature asymmetry measurements are commonly used to assess healing of Charcot neuro-osteoarthropathy.[18] **A review of 19 studies reported Charcot affected limbs to be 1.6 to 8.0 °C warmer than the opposite limb.** Current DFU risk monitoring protocols would not be definitive in individuals with diagnosed Charcot.

Personal baseline temperature asymmetry algorithm

Orpyx's baseline temperature asymmetry algorithm personalizes temperature monitoring by tracking temperature asymmetries relative to standard asymmetry thresholds and deviations from an individual's baseline. Combining personalized temperature asymmetry thresholds with the standard 2.2°C temperature asymmetry warning threshold represents a key advancement in personalized care.

Contributors to the personal baseline temperature asymmetry algorithm include both the magnitude of- and day-to-day variation of temperature asymmetries at each individual foot location over a predetermined time window. If an individual displayed a consistent temperature asymmetry greater than 0.5°C, the user's personalized thresholds are adjusted to reflect the baseline temperature asymmetry. Algorithm parameters were optimized based on a dataset of 361 Orpyx users, with the goal of identifying the shortest baseline time window that accurately represented an individual's personal baseline temperature asymmetry.

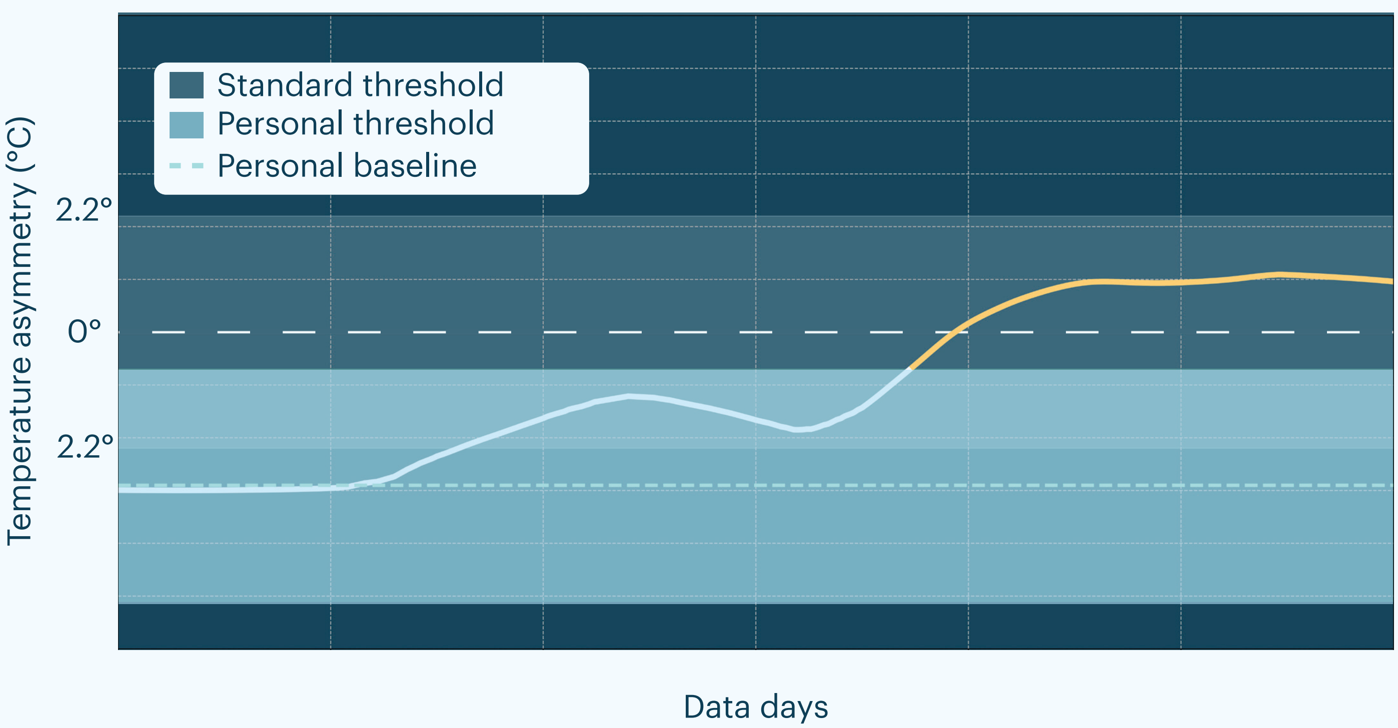
Remote patient monitors are empowered to leverage baseline data to individualize the monitoring plan. Individual patient circumstances, as determined by clinical history and RPM assessment, inform decisions to respond to standard asymmetry thresholds, personalized thresholds, or both.

The most meaningful clinical engagements start with the most personalized data.

Key takeaways:

A personal threshold will be set for individuals with consistent temperature asymmetry at baseline

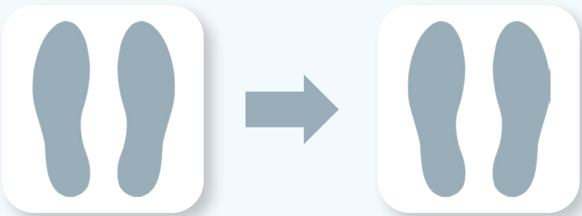
Standard and personal threshold will be equal for individuals with symmetric temperature at baseline



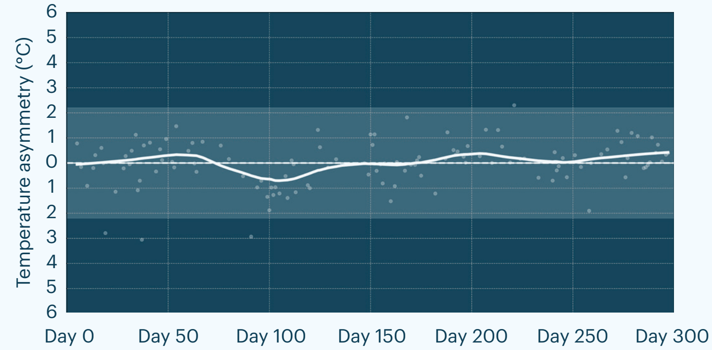
Plantar temperature trends

Illustrative plantar temperature asymmetry trends are shown below. These examples demonstrate that personal thresholds can be an additional indicator of a health status change that population thresholds alone can miss. For an individual at risk of DFU development, personalization provides an opportunity to flag changes in a patient's foot health. If an individual is symmetric at baseline, standard asymmetry thresholds are appropriate.

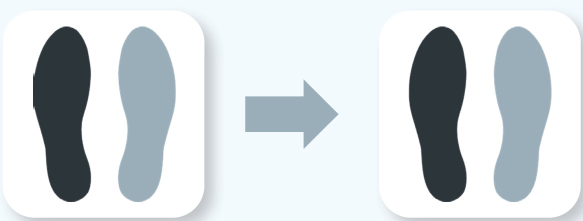
Symmetric at baseline → ***No deviation*** from standard threshold



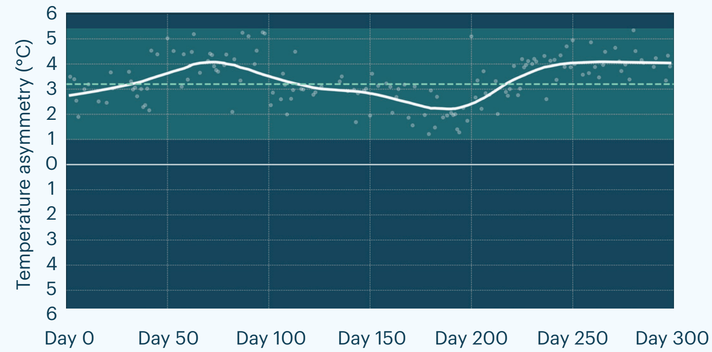
Standard asymmetry thresholds are appropriate



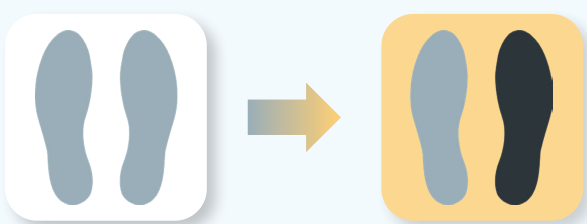
Asymmetric at baseline → ***No deviation*** from personal threshold



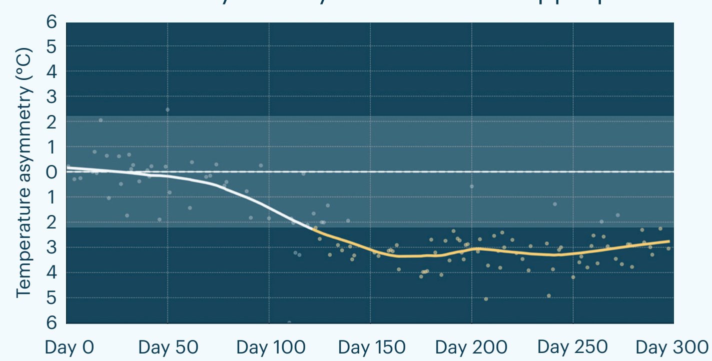
Personal threshold reduces false positive risk



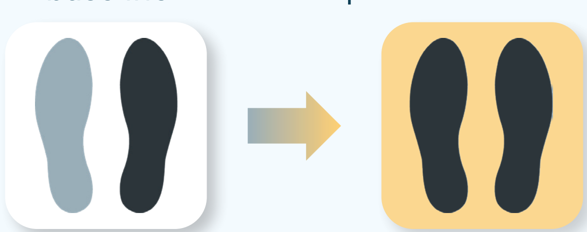
Symmetric at baseline → ***Deviation*** from standard threshold



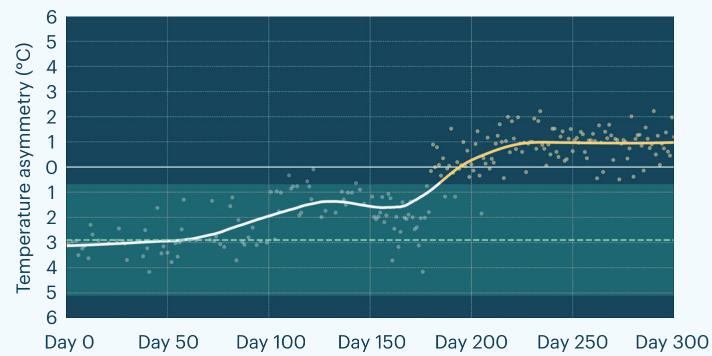
Standard asymmetry thresholds are appropriate



Asymmetric at baseline → ***Deviation*** from personal threshold

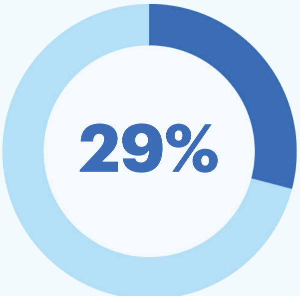


Personal threshold reduces false negative risk



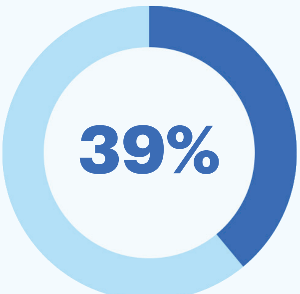
Clinical implications

Outcome #1: Accommodate patients with comorbidities that confound plantar temperature



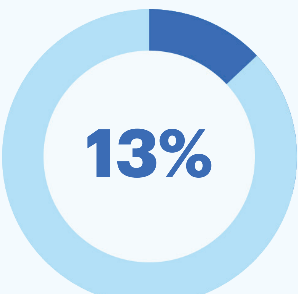
29% of users enrolled in the Orpyx program had a baseline temperature asymmetry >0.5°C at one or more foot locations (total users =361). Baseline asymmetries smaller than 0.5°C are not adjusted for because healthy controls have been shown to have an average contralateral plantar temperature variance of ~0.5°C.[19]

Outcome #2: Personal threshold reduces the risk of false positive temperature concerns



39% of users with a baseline temperature asymmetry would have been at risk of generating false positive temperature concerns. Personalizing temperature monitoring reduces unnecessary escalations to the provider, minimizing burden on the healthcare system.

Objective #3: Personal threshold de-risks false negatives with a naturally cooler limb



13% of users with a baseline temperature asymmetry would have been at risk of false negative temperature deviation warnings. Personalizing temperature monitoring supports identifying trending changes in a patient's foot health status, irrespective of a patient's baseline temperature asymmetry magnitude, that may be indicative of a developing DFU.

Broader impact and limitations

Why personalized medicine?

The use of both standard and personalized health data thresholds is becoming common in health and wellness tools. For instance, an individual using a wearable to monitor their sleep, may compare their total sleep time to population targets (e.g., 8 hours) as well as their own typical patterns (e.g., improving from 6 to 7 hours of sleep). Similar paradigms are well suited for chronic disease management, as the rise of "personalized medicine" aims to account for inter-individual variations in disease progression. **Digital health solutions hold great promise for supporting providers to personalize the way they treat, monitor, or prevent disease for an individual.**[20]

What's next for personalized temperature monitoring?

Ongoing research efforts are necessary to prove that personalized plantar temperature monitoring, or other personalized aspects of diabetic foot health management, outperform traditional strategies. **Clinical studies evaluating the sensitivity, specificity, and lead time of DFU prediction with personalized foot temperature monitoring will pave the way for ongoing innovation in the digital management of diabetic foot health.**

Limitations

As with any leading-edge technology, there are certain unknowns that are currently limitations, but may soon present as opportunities. **While baseline temperature asymmetry adjusts the asymmetry threshold values, it does not adjust for the total acceptable temperature range - an asymmetry event is still defined as a 2.2°C asymmetry from the individual's personalized baseline.**

Longitudinal algorithms, such as the baseline temperature asymmetry algorithm, use data available over a history of time individualize decision making. Therefore, a baseline temperature asymmetry will not be calculated for users who do not meet the minimum adherence criteria.

The baseline temperature asymmetry algorithm is biased by the patient's health circumstances, and resulting plantar temperatures, during the baselining time window. Data is always contextualized by the patient circumstances to ensure clinically relevant sources of inflammation at time of baselining are not overlooked.

Conclusion

With the addition of the baseline temperature asymmetry algorithm, Orpyx is leading the way in personalizing plantar temperature monitoring to the individual. Leveraging plantar temperature data collected from Orpyx's flagship sensory insole, monitoring for plantar temperature data trends of concern no longer has to be a one-size-fits-all solution.

Quantifying baseline temperature asymmetries creates visibility around how a patient's unique circumstances may confound standard temperature asymmetry thresholds.

With the personal baseline temperature asymmetry algorithm, individuals with diabetes that are burdened with other comorbidities are no longer excluded from plantar temperature monitoring protocols, rather they are supported by algorithms personalized to them.

Orpyx is dedicated to advancing the science behind digital health solutions that enable and reinforce diabetic foot health management guidelines, underscoring its mission to extend healthspan for people living with diabetes.

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