# Evaluating the Impact of a Remote Monitoring Service on Limb Salvage Outcomes in Diabetic Foot Management and Care

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## Background

Diabetic Foot Ulcers (DFUs) are associated with high morbidity and mortality. After experiencing a DFU, approximately 40% of individuals develop a subsequent ulcer within 12 months[1]. Each year in the USA, over 86,000 amputations occur because of DFUs[2]. Evidence suggests remote temperature monitoring (RTM) may reduce DFU recurrence. The addition of remote visual monitoring (RVM) to RTM may further reduce DFU recurrence and severity.

To determine the impact of RVM with RTM, we evaluated use of a "smart scale" home-based device that remotely captures images and temperature of the soles of the feet with each use. This data is used to detect risk factors associated with developing a DFU or other complications. If risk is detected, users, and if necessary, their providers, are alerted to support early intervention and resolution.

### Remote Thermovisual Foot Scanner



### Scan (Images and Temperature)
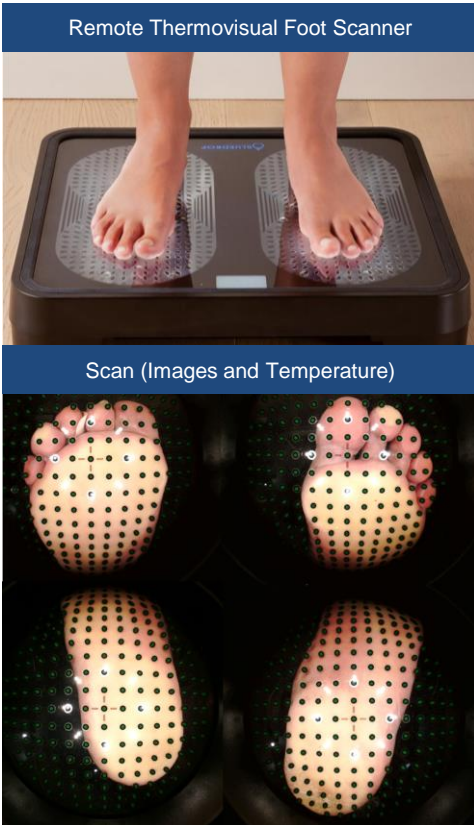


## Methods

### Enrollment

Individuals with diabetes, peripheral neuropathy and a history of diabetic foot ulcer (including varying levels of amputation) were referred by their physicians. A foot scanner was delivered to their home, and each individual received at least one onboarding call to set-up scanner and communicate program expectations (use 3 times / week or more). A subset of 34 patients (2,762 scans) were analyzed.

### Monitoring

During the program, if individuals did not scan for 3 consecutive days, they were reminded by SMS or phone, depending upon their elected preference. As individuals scanned, we analyzed the image and temperature data to assess risk based on a pre-defined clinical policy and inspection protocol developed using generally accepted standards. Risks were classified into 3 primary categories (see right):

| Risk | Examples | Action |
|---|---|---|
| ✅ Stable | Stable Callous, Known Deformity | **Monitor for Change** \| Noted in record, assessed for change |
| ⚠️ Elevated | New Callous, Soiling, Foreign Object, Excessive Dryness | **Patient Coaching** \| Notice to patient in preferred contact method. Suggested non-clinical intervention based on protocol |
| 🚨 High | Wound, Bleeding, Penetrating Object, Persistent Hot Spot, Acute Deformity | **Escalate to HCP** \| Advice to patient to protect affected area. Standard report to HCP in preferred contact method. |

### Program Breaks

Individuals scheduled breaks if away from home or experiencing a clinical issue prohibiting safe use of the scanner. During breaks, monitoring team encouraged attention to foot health and timely return to use of scanner when appropriate.

## Data and Representative Case Analysis

| Days Monitored → | Pre | 1-30 | 31-60 | 61-90 | 91-120 | 121-150 | 151-180 | >180 | Total |
|---|---|---|---|---|---|---|---|---|---|
| **Patients** | 34 | 34 | 33 | 30 | 27 | 19 | 13 | 12 | 34 |
| Days Between Scans[3-4] | | 1.4 | 1.6 | 1.6 | 1.6 | 1.7 | 1.8 | 1.9 | 1.6 |
| **Issue Detection and Monitoring** | | | | | | | | | |
| Scans / Patient | | 21.3 | 16.6 | 16.2 | 14.4 | 13.3 | 14.6 | 14.6 | 81.2 |
| Scans w/ Observations | | 7.9 | 6.4 | 8.9 | 9.9 | 9.6 | 11.6 | 12.6 | 44.1 |
| *Visual* | | 99% | 98% | 98% | 99% | 100% | 99% | 97% | 98% |
| *Temperature Alone* | | 1% | 2% | 2% | 1% | 0% | 1% | 3% | 2% |
| Monitor | | 6.0 | 5.2 | 7.6 | 8.7 | 8.7 | 10.7 | 11.1 | 37.5 |
| Coaching | | 1.5 | 1.0 | 0.9 | 1.0 | 0.8 | 0.7 | 0.9 | 5.1 |
| Internal Clinical Review | | 0.4 | 0.2 | 0.1 | 0.1 | 0.1 | 0.2 | 0.5 | 1.0 |
| HCP Escalation | | 0.1 | 0.1 | 0.3 | 0.1 | 0.1 | 0.1 | 0.1 | 0.5 |
| **Engagement** | | | | | | | | | |
| Contacts / Patient | | 4.3 | 3.6 | 3.3 | 3.2 | 2.8 | 2.1 | 2.3 | 3.1 | 19.3 |
| Onboarding | | 4.0 | 0.9 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 4.9 |
| Admin | | 0.3 | 0.3 | 1.0 | 0.9 | 0.7 | 0.6 | 0.7 | 0.8 | 1.6 |
| Coaching | | 0.0 | 1.9 | 1.8 | 1.6 | 1.6 | 1.3 | 1.4 | 1.6 | 8.1 |
| Compliance | | 0.0 | 0.2 | 0.5 | 0.8 | 0.4 | 0.3 | 0.2 | 0.7 | 2.2 |

### Case Study A - Detection and mitigation of Elevated-Risk situation via non-medical coaching, without need for HCP intervention.

Foreign objects (guitar plectrum, hair) in Sep 7 scan. Coaching provided to remove object and stress importance of not walking barefoot. No issues in subsequent scans.
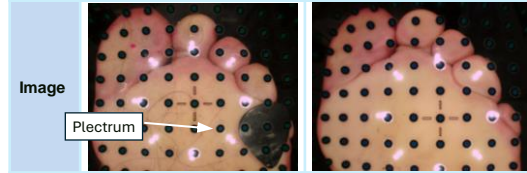


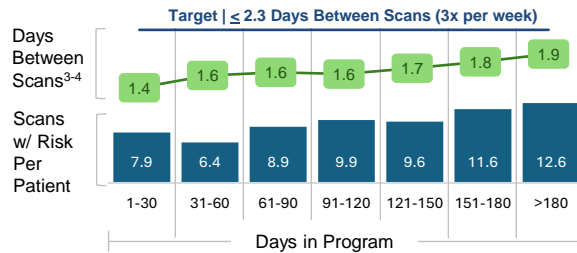| | | |
|---|---|---|
| **Date** | Sep 7 | Sep 11 |
| **Risk** | Elevated ⚠️ | Stable ✅ |
| **Action** | Coaching | Monitoring |

### Case Study B – Detection and mitigation of High-Risk situation by alerting HCP to issue, facilitating early intervention before further tissue deterioration occurs.

Dry blood visible adjacent to lesion (Wagner 1) on patient's right heel on May 2. Alert sent to HCP, visit scheduled ASAP. Treatment provided on May 5. Area bandaged till June 10. Area stable from June 12 and bandage no longer required.
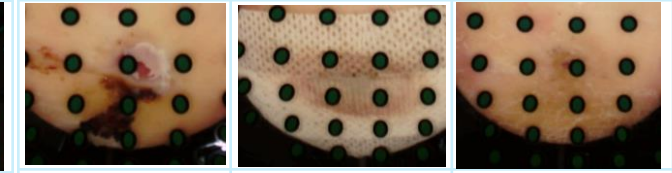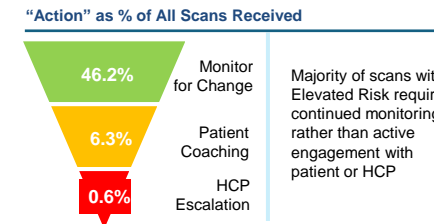


| | | | |
|---|---|---|---|
| **Date** | May 2 | May 5 – Jun 10 | Jun 12 |
| **Risk** | High 🚨 | Elevated ⚠️ | Stable ✅ |
| **Action** | Alert HCP | Monitoring | Monitoring |

## Patient Use and Risk Detection



**Target | ≤ 2.3 Days Between Scans (3x per week)**

Days Between Scans[3-4]: 1.4, 1.6, 1.6, 1.6, 1.7, 1.8, 1.9

Scans w/ Risk Per Patient: 7.9, 6.4, 8.9, 9.9, 9.6, 11.6, 12.6

Days in Program: 1-30, 31-60, 61-90, 91-120, 121-150, 151-180, >180

## Action for Elevated-Risk Scans

**"Action" as % of All Scans Received**



- 46.2% — Monitor for Change
- 6.3% — Patient Coaching
- 0.6% — HCP Escalation

Majority of scans with Elevated Risk require continued monitoring rather than active engagement with patient or HCP

## HCP Escalations

**Timing of HCP Escalations for 8 users**

| User ID | Days Monitored | 1-30 | 31-60 | 61-90 | 91-120 | 121-150 | 151-180 | >180 | Total |
|---|---|---|---|---|---|---|---|---|---|
| 16 | 274 | | | 1 | | | | 1 | 2 |
| 20 | 256 | | 3 | 1 | | | | | 4 |
| 21 | 224 | 1 | | | | | | | 1 |
| 24 | 207 | | | 1 | | 1 | | | 2 |
| 25 | 204 | 1 | 2 | 1 | | | | | 4 |
| 30 | 181 | | | | 1 | | | | 1 |
| 33 | 114 | | 1 | 1 | | | | | 2 |
| 50 | 100 | | 1 | | | | | | 1 |
| **Total** | | 2 | 2 | 8 | 2 | 1 | 1 | 1 | 17 |

High risk issues requiring HCP escalation detected across the study duration, supporting the need for ongoing monitoring of high-risk individuals

## Observations

▷ Sustained high levels of Patient Use were observed, with average number of scans per week above recommended throughout study duration, indicating durable compliance.

▷ The proportion of Scans With Risk increased with duration in study, supporting need for long term use for high-risk individuals

▷ 6.9% of scans had Elevated-Risk factors requiring intervention[5]. Of these, 91% were resolved directly with patient, while only 9% required escalation to the HCP
  - 8 of 34 patients (24%) required HCP Escalation
  - 174 scans (6.3%) required patient coaching, 17 required HCP Escalation (0.6%)

▷ HCP Escalations were required throughout the study duration, indicating the ongoing threat of new High-Risk situations occurring, providing further evidence of the need for long term monitoring of high-risk individuals.

## Discussion

The observational data presented suggest an easy-to-use smart scale, that combines remote temperature monitoring (RTM) with remote visual monitoring (RVM), may reduce the burden of diabetic foot complications in high-risk patients when accompanied by a pragmatic monitoring service.

Of 34 patients monitored, 29 (85.3%) required Coaching and/or HCP Escalation, averaging 1.07/ Coaching or HCP Escalation Actions per patient per 30 days. Of 2,762 scans, 17 (0.6%) required HCP Escalation, suggesting the monitoring service is effective in mitigating risk without burden to HCP and staff.

The case studies further support how the combination of the device and service help to resolve non-clinical risks, while alerting to likely clinical risks for early diagnosis/intervention. Case A shows how non-clinical risks are resolved, preventing a likely clinical issue if unobserved. Case B shows how clinical risk is immediately escalated to the HCP for early diagnosis and intervention. Ongoing monitoring in Case B highlights ability to manage ongoing risk in partnership with the HCP.

Overall, early detection of risk factors using consistent capture of images and temperature data may mitigate progression of risks to clinically and economically significant complications. In fact, all ulcers diagnosed by physicians following an escalation were grade 1 or lower according to the Wagner Grading system, suggesting significant economic benefit. Further analysis with a higher number of study subjects over a longer period of time would be necessary to statistically quantify the benefit and correlate to the monitoring solution described herein.

1. SOURCE: Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med 2017 376:2367-2375
2. SOURCE: LEA - Burden Toolkit. (n.d.). CDC.gov. https://nccd.cdc.gov/Toolkit/DiabetesBurden/Hospitalization/Lea
3. DEFINITION: Patients were provided a foot scanner at no cost but were not paid / incented to participate beyond the intrinsic foot health benefits intended.
4. DEFINITION: Program Break days in which a patient was away from their home or restricted from scanning due to a medical issue are excluded from these calculations.
5. DEFINITION: Risk requiring engagement with patient and/or provider, excludes risks monitored without engagement