White Paper 1 | March 2025

Exploring the Impacts of a Holistic Remote Monitoring Program for the Diabetic Foot Using a Novel Thermovisual Monitoring Device

Diabetic Foot Ulcers (DFUs)

One of the most devastating complications of diabetes

25% of people with diabetes will develop an ulcer[1]

Annually in the USA

1.6M+
Diabetic foot ulcers[2]

100k
Diabetes related amputations[3]

$17B+
Excess direct cost[4]

Why do DFUs Occur?

50% of people with diabetes suffer from nerve damage in their feet known as peripheral neuropathy[5].

Normally, healthy individuals feel pain when their feet experience damage, such as cuts or blisters, and they take action; changing shoes, resting, or applying simple care at home. But for patients with neuropathy, this damage goes unnoticed and untreated, until an ulcer has developed, or even until it is infected.

25% of people with diabetes will develop a diabetic foot ulcer at some point in their life – leading to 1.6M ulcers per year in the US[2].

Exacerbated by peripheral vascular disease, average healing time is 3 months[6]. However, because most ulcers are not caught until they are deep, or infected, 30% will remain un-healed even after a year, and 15% will lead to amputation[7,8].

Each year diabetes causes 100k amputations in the US – it is the leading cause of amputation. After amputation, the 5-year mortality rate is 46% - higher than most forms of cancer.

Complete loss of feeling in feet (peripheral neuropathy) → **Individuals don't detect damage on feet – until too late** → **Minor skin damage progresses into ulcers** → **Ulcers slow to heal due to peripheral arterial disease**

DFUs create a large burden for the patient and the broader healthcare system

Understanding the Cost of Diabetic Foot Ulcers

The Human Cost of Recurrence

After a diabetic foot ulcer (DFU) heals, the patient has a 30-60% annual risk of developing a subsequent ulcer[9]. Within 5 years up to 80% will have developed at least one subsequent ulcer[9].

The risk of recurrence is influenced by various factors, including overall health of the individual, management of diabetes, age and prior ulcer severity.

The ongoing impact recurring ulcers have on quality of life and wellbeing is profound, inhibiting individuals' mobility, ability to drive and / or work and adding strain to their personal finances.

40%+ **Recur Annually** Following First Ulcer[9]

15% Of ulcers lead to **Amputation**[8]

46% **5-year Mortality** Post amputation[10]

The Dollars and Cents

The annual direct cost of DFUs in the US is upwards of $17B[4]. Each ulcer costs on average $31,000[11]. A driver of these costs is amputation, which, if required can balloon episode costs to over $100,000[3].

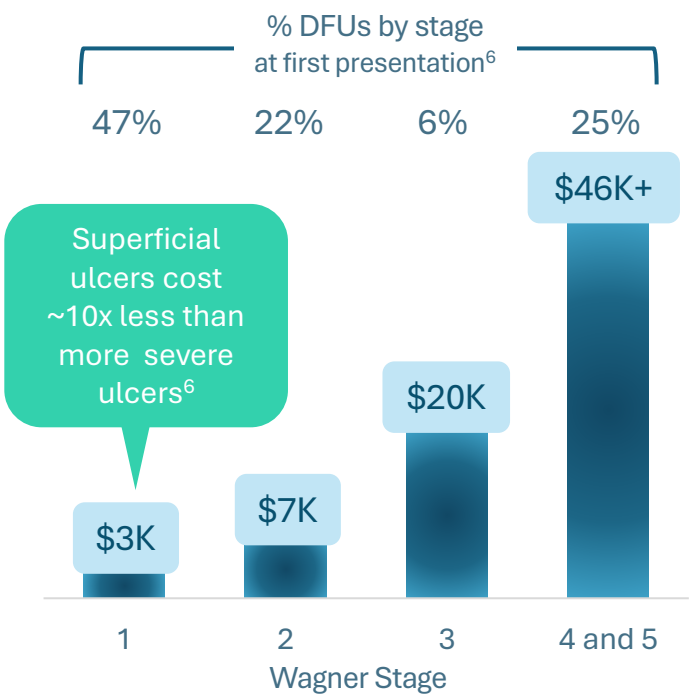
However, not all ulcers are equal when it comes to cost and outcomes. DFUs are commonly graded using the Wagner Grading System which classifies ulcers from Stages 1-5. With Stage 1 being a superficial ulcer, and Stage 4-5 being deep DFUs with gangrene.

Fig. 1 illustrates the current distribution and average cost associated with each Wagner DFU stage[6].

Stage 1 DFUs are associated with 10X less cost and half the risk of hospitalization and amputation[6]. However, 50% of ulcers are not caught until Stage 2 or later. 25% are not caught until after gangrene has set it and amputation is more likely[6].

This highlights an opportunity to reduce the cost of DFUs through early detection and interventions.

Average Cost per Episode for Wager Stage 1-5 Ulcers



Early identification and intervention can meaningfully impact outcomes and cost

A Solvable, but Challenging Problem

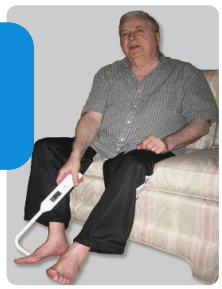
The Easy Answer? Check Your Feet, Everyday.

Self-assessment is the primary method for ulcer prevention and detection. At-risk individuals are instructed to conduct daily visual inspections. Those with highest risk may also be directed to use pressure or temperature sensing devices to help identify inflammation and early ulcer formation. Studies suggest daily temperature can prevent approximately 70% of ulcers[12-14].

1 Daily Visual Inspection

2 Daily Temperature Monitoring

Prevents 70% of foot ulcers
In 3 RCTs[12-14]



The Reality? It's Not So Easy...

A person's dexterity, flexibility, eyesight, pain and understanding of risk factors significantly impacts the effectiveness of self foot checks. For individuals using remote monitoring solutions that rely on temperature or pressure tracking, many become discouraged by unclear signals that lead to unnecessary clinic visits or the failure to detect an ulcer due to the absence of the necessary indicators at the DFU site.

In short, self-directed plans often lack consideration for the burden experienced by an individual to successfully execute. This is devastating given the potential for not only change, but elimination of the problem.

These real world limitations prevent at risk individuals from inspecting their feet, perpetuating the problem....

A Practical Approach Using a Familiar Form Factor

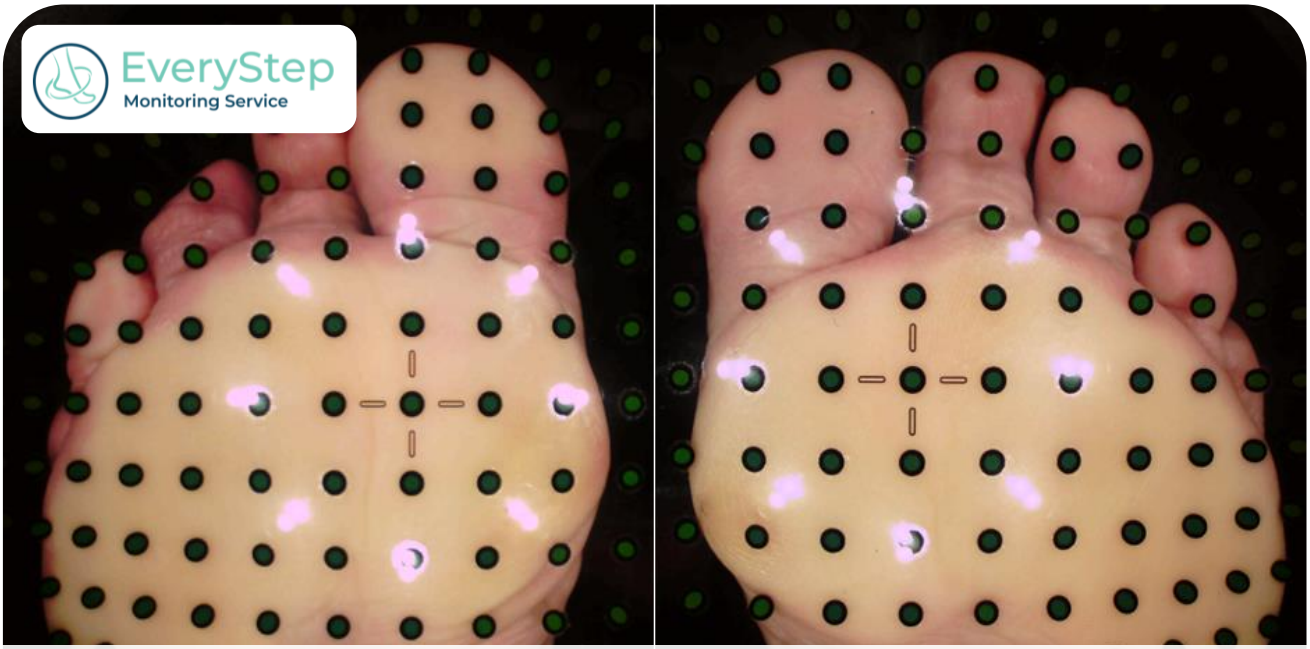
Daily visual and thermal foot inspections using a “smart scale” at home

Understanding the challenges with standard self-assessment techniques, Bluedrop Medical have developed a proprietary, home use foot scanner to inspect a user’s feet in a simple 30 second scan. Once per day, the user simply places their feet on the device to initiate the scan process, during which high resolution images and temperature data from the feet are captured. This data is securely transmitted to Bluedrop for analysis using a companion 4G router.

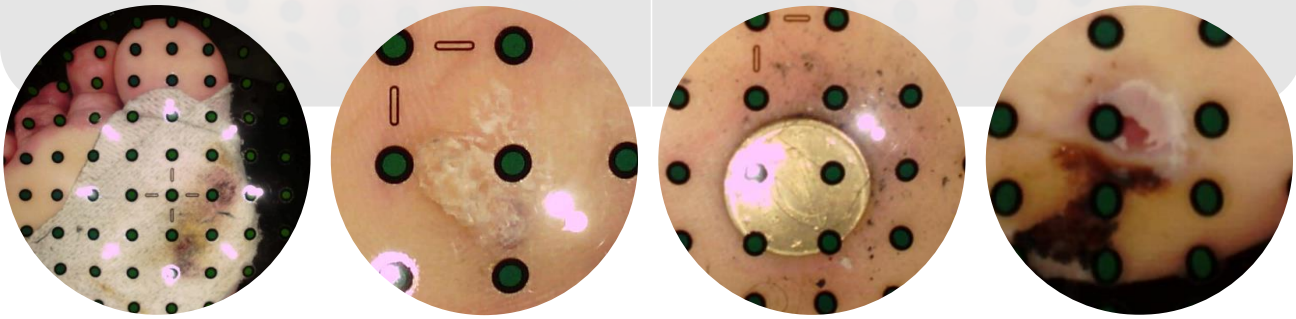
Images

Temperature

Weight



Within 24 hours, Bluedrop uses AI assisted software to inspect feet for signs of visual and temperature risks. Our team notifies users of risks identified that require attention and may escalate to their prescriber if clinical intervention is needed.



Nuanced Approach to Engagement and Risk Management

Monitoring and Engagement Framework

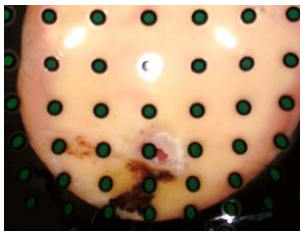
Scans are analyzed using a predefined clinical policy and inspection protocol, developed using widely accepted assessment standards. Our action based risk classification system ensures purposeful communication when needed, reducing unnecessary notifications to users.

RISK LEVEL	VISUAL	TEMPERATURE	ACTION
Stable	Known conditions requiring regular observation (e.g., calluses, deformities)	Single or Intermittent Hot Spot(s)	Monitor for Change, Educate as Needed to Maintain
Elevated	Emerging risks such as excessive dryness, foreign objects, small wounds / fissures or new calluses	Persistent or Worsening Hot Spot(s) over 2 or more consecutive scans	Notify User to Take Self-Care Measures, Escalate to Prescribe If Worsens
High	Critical issues such as wounds, bleeding, penetrating objects or acute deformities	N/A	Notify User to Protect and Seek Care, Escalate to Prescriber

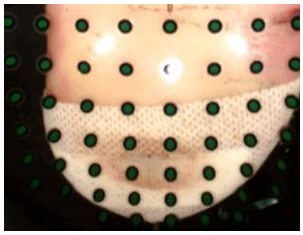
Application of Solution | Case Analysis Demonstrating Impact

The two cases below highlight how risks are identified and relayed to users for complication avoidance and early intervention. In some instances, risks are immediately escalated to a prescriber while others are escalated if a risk worsens. While these cases demonstrate timely escalation, only 1% of issues require escalation to a clinician for intervention while the vast majority are resolved directly with the user.

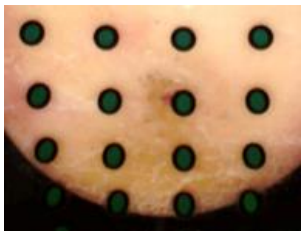
Case 1 | Recurring Wound Requiring Frequent Engagement to Limit Severity



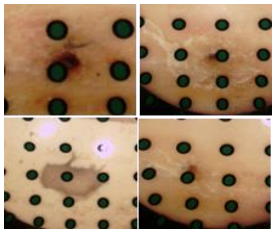
May 2
Dried Blood + Lesion
Risk | High
Action | Alert Patient, HCP



May 5 –June 10
Dressing Applied
Risk | Elevated
Action | Monitor for change



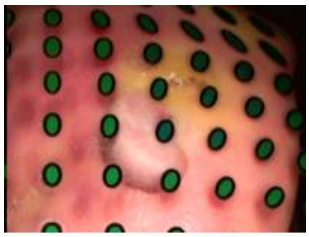
June 12
Healed/ Remission
Risk | Stable
Action | Ongoing monitoring



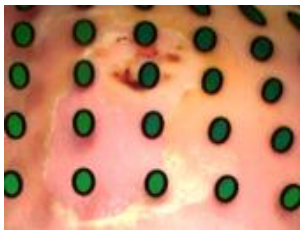
June 24 – October 26
3 Additional Escalations for Worsening of Same Issue, All Detected Early

Case 2 | Worsening Risk, Escalation, User Engagement to Resolution

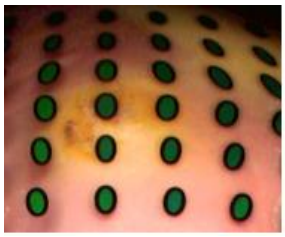
May 21
Lesion
Risk | Stable
Action | Monitor for change



May 22
Blistering, Lesion
Risk | High
Action | Alert Patient, HCP



May 30
Post Clinical Intervention
Risk | Elevated
Action | Monitor for Change



June 28
Healed/ Remission
Risk | Stable
Action | Ongoing monitoring

Easy to Use Device + Practical Engagement Model = Results

Early Experience Supports Positive Impact to Cost of DFUs

User Compliance

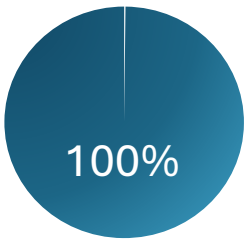
The basis for success in any remote monitoring program is sustained user compliance. This creates the needed data for effective engagement and management of the monitored population. The experience to date for those monitored using Bluedrop's solution suggests persistent high compliance, with users scanning 4+ times per week, exceeding the minimum recommended use of 3 scans per week. This enables near real time risk detection and early intervention by seeing feet approximately every other day.

Month in Program	1	2	3	4	5	6	6+	**Total**
Average Scans/Week	5.2	4.5	4.3	4.4	4.2	3.9	3.6	**4.4**

Risk Detection and Engagement

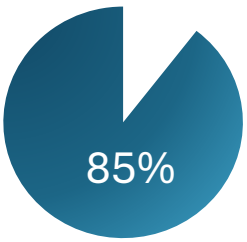
As expected with the high risk population monitored, over half (54%) of scans reviewed to date contained at least 1 risk factor that required either *ongoing observation for change, contact with the patient for preventative action or escalation to the treating prescriber for early clinical intervention*. For every 30 days monitored, patients are contacted to notify of a material risk factor that requires attention 1.5 times on average.

% of Users with Risk Factor
Over time in program



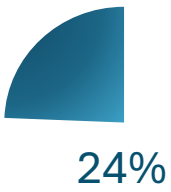
Avg 9.3 scans with risk per user every 30 days

% of Users Requiring Coaching
Over time in program



Avg 1.5 coaching engagements per user every 30 days

% of Users Requiring HCP Escalation
Over time in program

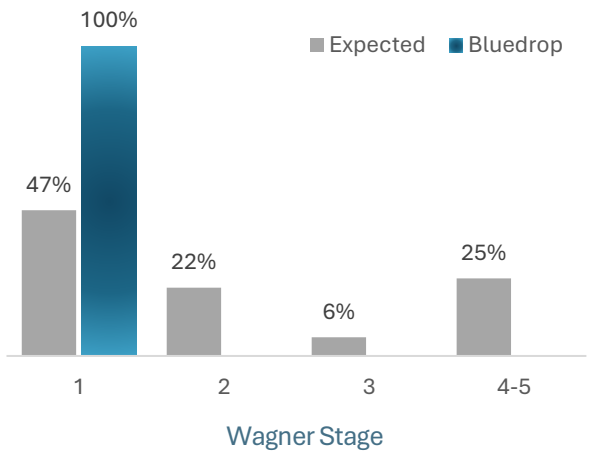


< 1% of risks across all users required escalation to HCP

Impact

To date 24% of patients using the Bluedrop system have been referred to their prescriber for elevated risk at some point. 100% of ulcers detected were superficial Stage 1. In a typical population on first presentation, 53% of ulcers would be significant, Stage 2 or higher ulcers, and 25% would be infected. Superficial ulcers are on average 10 times lower cost to treat than more significant Stage 2+ ulcers. These early results suggest that the combination of visual and thermal monitoring, with proactive engagement when risk is identified can improve the current cost and burden of diabetic foot ulcers. While this analysis is observational, Bluedrop has initiated a clinical trial to further demonstrate the impact the monitoring solution may have on the cost of DFUs. More information on the trial can be found at clinicaltrials.gov/study/NCT06782386.

DFU Severity at Time of Detection[6]
100% of DFU detected at Stage 1 when using Bluedrop



Conclusion

Daily at home temperature and visual monitoring using Bluedrop Medical's device offers a way to remotely monitor patients for risks that may lead to diabetic foot ulcers. Compliance to recommended use of the device by patients was high, with 4.4 scans per week on average. This highlights both the ease of use of the Bluedrop device, the efficacy of Bluedrop Medical's engagement program, and the overall level of engagement participants have with their foot care.

Due to the high-risk nature of these patients, 100% of patients had at least 1 scan where a risk was observed. 85% of participants required at least 1 coaching session, with the Bluedrop engagement team, over their time in the program. However, only 24% of patients had a risk that was not possible to address remotely, and/or warranted escalation to the healthcare provider. These results highlight the high-risk nature of these patients, and the ability of the monitoring program to effectively identify risks early, act on this data through further monitoring or coaching, and to effectively escalate to healthcare providers when needed.

Despite the limited nature of the analysis presented, in terms of sample size and duration, early signs indicate the efficacy of the system at improving outcomes and reducing costs. Of the ulcers identified with the system, 100% were superficial and classed as Stage 1 on the Wagner Scale and referred to the health care provider at this point. Typically, only 47% of ulcers are first seen by healthcare providers at this superficial stage, with 25% of ulcer not seen until gangrene has set in. Early identification, and early intervention is critical to improve outcomes and reduce cost. With Stage 1 ulcers costing 10 times less than the average cost of Stage 2-5 ulcers, these results indicate an early signal on the potential impact remote thermovisual monitoring can have on improving cost of care.

Buedrop Medical has an active clinical trial which will provide further evidence to support the impact of remote thermovisual monitoring on outcomes and cost – through early identification and prevention of significant ulcers

Interested? How to find out more:

- **Website:** www.bluedropmedical.com
- **Email:** info@bluedropmedical.com

Bluedrop Medical | On a mission to end unnecessary diabetic amputations

Appendix | Analysis Summary and Aggregate Data

Analysis Summary

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 total of 37 patients were monitored during the analysis period, with a subset of 34 patients (2,762 scans) included in the analysis. Exclusions included 2 monitored for less than 30 days and 1 unable to use monitoring device due to non-foot related health issue. Individuals were monitored between March – November 2024. Individuals were not compensated for their participation but were provided the monitoring solution at no cost. Referring physicians were also not compensated.

Table 1 | Summary of Monitoring Activity

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
Average Scans / Week		5.2	4.5	4.3	4.4	4.2	3.9	3.6	4.4
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	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

Table 2 | Clinical Escalations per User

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**

Definitions

Table1

Days Monitored refers to 30 days increments of time individuals were monitored in the program. "Pre" refers to time prior to monitoring in which outreach for on boarding and administrative coordination occurred.

Patients refers to number of users included within the Days Monitored period for analysis based on time monitored.

Scans/Patient refers to successful uses of device by users for each time period.

Scans w/ Observations refers to scans annotated with foot risk. Risk Observations are classified as Visual or Temperature Alone depending upon method of risk detection. They are separately classified by required action according to monitoring policy.

Contacts / Patient describes contacts by type to each patient.

Table 2

User ID refers to the unique ID used within the analysis. Days Monitored refers to the total days monitored at time of analysis with identical time segments across the table headings.

Escalations refers to number of escalations for each user to a prescriber for clinical intervention.

References

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