

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION**

PODIMETRICS, INC.

Plaintiff,

v.

BLUEDROP MEDICAL, LTD.

Defendant.

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CASE NO. 3:24-CV-00188

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Podimetrics, Inc. (“Podimetrics”), by and through its attorneys, alleges the following for its complaint against Bluedrop Medical, Ltd. (“Bluedrop”):

NATURE OF THE ACTION

1. This action seeks legal and equitable relief based on Bluedrop’s willful infringement of Podimetrics’ U.S. Patent Nos. 9,095,305, 9,259,178, 9,271,672, and 9,326,723 (individually and collectively, “Patents-in-Suit”).

PARTIES

2. Podimetrics is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 100 Dover Street, Somerville, Massachusetts 02144.

3. Upon information and belief, Bluedrop is a limited liability company organized and existing under the laws of Ireland with its headquarters located in Galway, Ireland, and with its principal (and only) place of business in the United States located at

1201 Fannin Street, Suite 262, Houston, Texas 77002.

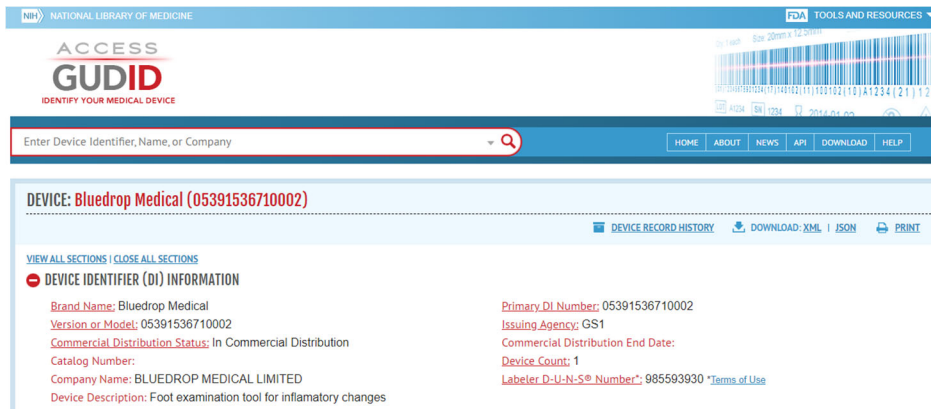
JURISDICTION AND VENUE

4. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271, *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Bluedrop in this action because Bluedrop has committed acts within this District giving rise to this action and has established minimum contacts with this forum such that the exercise of jurisdiction over Bluedrop would not offend traditional notions of fair play and substantial justice.

6. Bluedrop, directly and/or through subsidiaries, employees, intermediaries, or trade names, has committed and continues to commit acts of infringement in this District by, among other things, importing, offering to sell, and selling an instrumentality that infringes the Patents-in-Suit. Moreover, Bluedrop has a physical presence in this District from which, upon information and belief, it offers to sell and sells an instrumentality that infringes the Patents-in-Suit.

7. According to the U.S. National Institute of Health’s (“NIH”) National Library of Medicine website (“Access GUDID”), Bluedrop’s “foot examination tool for inflammatory changes,” which is the accused instrumentality, is “in commercial distribution” by Bluedrop:



See Access Global Unique Device Identification Database, Bluedrop Medical

(05391536710002) (available at

<https://accessgudid.nlm.nih.gov/devices/05391536710002>) (visited June 24, 2024). Upon information and belief, the information contained in the Access GUDID is “key device information” for the accused instrumentality that Bluedrop submitted to the Federal Drug Administration (“FDA”). See, e.g., <https://accessgudid.nlm.nih.gov/about-gudid> (visited June 24, 2024).

8. Bluedrop’s website contains a printable “order form” for the accused instrumentality. See https://bluedropmedical.com/wp-content/uploads/2024/02/BluedropOrderForm_8Jan24-1.pdf (visited June 24, 2024). That form indicates that completed order forms can be faxed to a telephone number with a Texas area code. *Id.* In addition, Bluedrop’s website instructs clinicians who are interested in receiving “resources” relating the accused instrumentality to contact Bluedrop’s offices located in Houston, Texas. See <https://bluedropmedical.com/provider-resources/> (visited June 24, 2024).

9. According to Bluedrop’s website, the only location in the United States

where “patients, clinicians, healthcare providers, or anyone interested in what we are doing” can contact Bluedrop at its offices in Houston, Texas:

Contact Us

We are always looking to hear from and patients, clinicians, healthcare providers or anyone interested in what we are doing.

✉ info@bluedropmedical.com

☎ 1-855-453-8707

📍 BLUEDROP RPM 1201 Fannin St, Houston, TX 77002 USA

📍 Ground Floor, Unit 4, Ballybrit Business Park, Galway, Ireland H91 A4XW

See <https://bluedropmedical.com/contact/> (visited June 24, 2024).

10. According to Bluedrop’s public materials, two members of Bluedrop’s “leadership team” and its “U.S. Leadership” – Chris Sandroussi, Chief Commercial Officer, and Ron Scott, MD, Medical Director – are based in Bluedrop’s Houston, Texas office:

Leadership Team

US Leadership (Houston, Texas)

Chris Sandroussi, CCO
Texas, USA
Accomplished GTM and commercial leader, driving broad access and adoption. Experienced leader in digital health, wound care & reimbursement. Former: KCI/Acelity - Led various ops, commercial, strategic functions; 3M - Led Global Medical Solutions Strategy and Business Development.

Ron Scott MD, Medical Director
Texas, USA
Passionate, accomplished wound care leader and innovator. Pioneer in modern wound care over 30-year career. Established first comprehensive, fully integrated wound treatment facility in the North Texas in 1985; one of the first such facilities in the US.

Irish Leadership (Galway, Ireland)

Chris Murphy, CEO/Founder
Ireland
Medtronic
Visionary entrepreneur, patient advocate and innovation leader. Founded Bluedrop with goal of preventing avoidable diabetic amputations. 10 years' experience in medical device product development. Raised over \$15M for Bluedrop. 7 patents. Former Medtronic R&D.
Total team size: 20 USA + Ireland

Simon Kiersey, COO/Founder
Ireland
Medtronic
Dynamic business leader, with expertise across the medical device innovation lifecycle. 15 years' experience leading development of electronic medical devices. 10 journal publications, 5 patents. 8 clinical studies.

Gavin Corley PhD, CTO
Ireland
VASCARD Viteco
Customer-centric innovation leader, focused on intuitive, useful solutions. 15 years' experience leading development of electronic medical devices. Former Vascard CTO. 10 journal publications, 5 patents. 8 clinical studies.

Bluedrop Medical

See <https://www.youtube.com/watch?v=klAmFikWZj4> (visited June 24, 2024).

11. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400. Bluedrop maintains a regular and established place of business in this District from which it offers to sell and sells products that infringe the Patents-in-Suit.

12. Bluedrop has also transacted business in this District and has committed acts of direct infringement in this District.

**PODIMETRICS' INNOVATION AND
PROTECTION OF ITS TECHNOLOGY**

13. Podimetrics is a tech-enabled services company dedicated to preventing diabetic amputations, one of the most debilitating and costly complications of diabetes. Using early detection and prevention of diabetic foot ulcers, Podimetrics' mission is to enable patients with diabetes to lead independent and fulfilling lives. Podimetrics offers a personalized touchpoint in the homes of at-risk patients by combining proven, simple-to-use technology, remote monitoring, personalized support, and communication with providers to create patient affinity and program adherence.

14. Podimetrics' product, SmartMat™ and associated Podimetrics software (collectively, "SmartMat™") a device akin to a scale that uses thermometry-based monitoring to detect early signs of inflammation and provides alerts and recommendations (to patients and their health care providers):

Solution Features

FDA-cleared SmartMat™

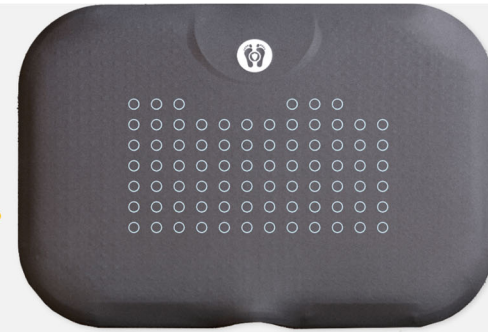
Easy to set up and use, scans feet in only 20 seconds/day



Solution Features

Thermometry-based monitoring and alerts

Clinically proven to help detect earliest signs of inflammation



Solution Features

Seamless provider collaboration

Automatic alerts, updates and personalized reporting for each enrolled member

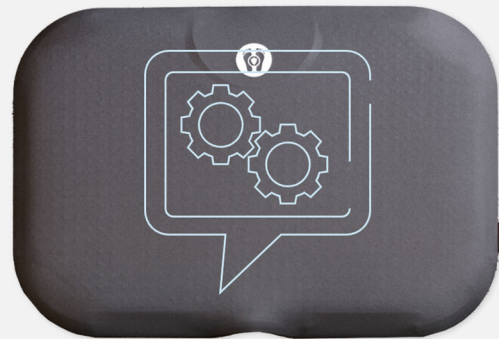
Two-way communication as needed to tailor interventions to your plan of care



Solution Features

Customizable patient support options As needed to best fit your member population and plan structure.

- Assisted program enrollment
- Monitoring and engagement calls
- Inflammation alerts
- Proactive, supported remediation



See. e.g., <https://www.podimetrics.com/patients/> (visited June 24, 2024).

15. Podimetrics' SmartMat™ is simple to use, FDA-cleared, and has the Seal of Approval from the American Podiatric Medical Association. The U.S. Department of Veterans Affairs ("VA"), health plans, and at-risk provider groups, among other institutions, have approved the use of SmartMat™ by their subscribers to help prevent amputations associated with complex diabetes. By combining cutting-edge technology with best-in-class clinical and patient support services, Podimetrics earns high engagement rates from patients and allows clinicians to save limbs, lives, and money – while keeping vulnerable populations healthy in their own homes. Currently, Podimetrics' SmartMat™ is used by patients in 49 of 50 states in the U.S. (except Alaska).

16. A study published in 2017 demonstrated that the Podimetrics' SmartMat™ detected 97% of non-traumatic plantar diabetic foot ulcers (*i.e.*, diabetic foot ulcers forming on the bottom surface of the foot) approximately 37 days before clinical presentation. *See* Robert G. Fryberg, Ian L. Gordon, Alexander M. Reyzelman, *et al.*, "Feasibility and Efficacy of a Smart Mat Technology to Predict Development of Diabetic Plantar Ulcers," *Diabetes Care* 1 July 2017; 40(7): 973-980 (available at <https://doi.org/10.2337/dc16-2294>) (visited June 24, 2024). To date, the SmartMat™ is the only remote monitoring technology for diabetic foot ulcers to have been evaluated for clinical accuracy.

17. In a peer-reviewed study involving a yearlong foot ulcer recurrence prevention program at four outpatient centers in the Mid-Atlantic U.S., Podimetrics' SmartMat™ reduced lower extremity amputations by 71%, (all-cause) hospitalizations by 52%, (all-cause) emergency department visits by 40%, and outpatient visits across all departments by 26%. *See* Isaac AL, Swartz TD, Miller ML, *et al.*, "Lower resource

utilization for patients with healed diabetic foot ulcers during participation in a prevention program with foot temperature monitoring,” *BMJ Open Diabetes Research and Care* 2020 (available at <https://drc.bmj.com/content/8/1/e001440>) (visited June 24, 2024). Further, in a study completed across 924 U.S. veterans treated within the VA healthcare system, the use of the SmartMat™ was associated with a 37% decrease in mortality within the first year of usage alone. See Alyson J. Lippman, Andrew K. Thomas, Anna Korpak, *et al.*, “Evaluation of Effectiveness of Remote Foot Temperature Monitoring for Prevention of Amputation in a Large Integrated Health Care System,” *Diabetes Care* 1 Aug. 2023; 46(8): 1164-68 (available at <https://doi.org/10.2337/dc22-1492>) (visited June 24, 2024).

18. Podimetrics has received many awards relating to its SmartMat™, including being named by Fast Company as one of the World’s Most Innovative Medical Device Companies for 2024, Number 140 on Deloitte’s 2023 fastest growing technology companies in North America for 2023 (up from Number 223 the previous year), Number 581 on the 2023 Inc. 5000 list of the fastest growing privately held companies in the world (up from Number 942 in 2022), the UCSF Health Award for the top consumer prevention company of 2021, the 2021 Massachusetts Innovation Network’s Robert J. Crowley Spirit of Innovation Eddie Award, a Fierce Innovation (Healthcare Edition) award in 2019, a Medical Design Excellence Award, and being named an AICPA service organization.

19. For more than ten years, Podimetrics has invested considerable time and resources to develop – and protect – intellectual property that allows its products, including SmartMat™, to offer unique advantages that no other product can.

20. On August 4, 2015, the United States Patent and Trademark Office

(“USPTO”) issued U.S. Patent No. 9,095,305 (the “’305 patent”), titled “METHOD AND APPARATUS FOR INDICATING THE EMERGENCE OF A PRE-ULCER AND ITS PROGRESSION.” The ’305 patent is valid and enforceable. A true and accurate copy of the ’395 patent is attached hereto as Exhibit 1 and is incorporated herein by reference.

21. Podimetrics is the owner and assignee of all rights, title, and interest in and to the ’305 patent and holds all substantial rights therein, including the rights to grant licenses, to exclude others, and to enforce and recover past damages for infringement of that patent.

22. Claim 1 of the ’305 patent is reproduced below:

1. A method of determining emergence of a pre-ulcer or progression of a known pre-ulcer on at least one foot of a patient, the method comprising:
providing one or more processors;
providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors;
generating, using the plurality of temperature sensors, a plurality of discrete temperature data values after receipt of the at least one foot;
forming, by at least one of the processors, at least one thermogram of the sole of each of the at least one foot from the discrete temperature data values, the thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole;
determining, by at least one of the processors, at any location within the at least one thermogram of the sole, whether the thermogram presents at least one of a plurality of prescribed patterns; and
producing, by at least one of the processors, output information indicating an emergence of a pre-ulcer or progression of a known pre-ulcer in the at least one foot, producing being a function of whether the thermogram is determined to present the at least one pattern.

Exhibit 1 at 16:39-63.

23. On February 16, 2016, the USPTO issued U.S. Patent No. 9,259,178 (the “’178 patent”), titled “METHOD AND APPARATUS FOR INDICATING THE EMERGENCE OF AN EMERGING ULCER.” The ’178 patent is valid and enforceable.

A true and accurate copy of the '178 patent is attached hereto as Exhibit 2 and is incorporated herein by reference.

24. Podimetrics is the owner and assignee of all rights, title, and interest in and to the '178 patent and holds all substantial rights therein, including the rights to grant licenses, to exclude others, and to enforce and recover past damages for infringement of that patent.

25. Claim 1 of the '178 patent is reproduced below:

1. A method of determining a risk of an ulcer emerging on at least one foot of a patient, the method comprising:
providing one or more processors;
providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors;
generating, using the plurality of temperature sensors, a plurality of discrete temperature data values after receipt of the at least one foot;
forming, by at least one of the one or more processors, at least one thermogram of a sole of each of the at least one foot from the discrete temperature data values, the at least one thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole of each of the at least one foot;
determining, by at least one of the one or more processors, at any location within the at least one thermogram of a sole of the at least one foot, whether the at least one thermogram presents at least one of a plurality of prescribed patterns; and
producing, by at least one of the one or more processors, output information indicating a risk of an ulcer emerging on the at least one foot, said producing being a function of whether the at least one thermogram is determined to present the at least one of the plurality of prescribed patterns.

Exhibit 2 at 16:31-56.

26. On March 1, 2016, the USPTO issued U.S. Patent No. 9,271,672 (the "'672 patent"), titled "METHOD AND APPARATUS FOR INDICATING THE EMERGENCE OF AN ULCER." The '672 patent is valid and enforceable. A true and accurate copy of the '672 patent is attached hereto as Exhibit 3 and is incorporated herein by reference.

27. Podimetrics is the owner and assignee of all rights, title, and interest in and

to the '672 patent and holds all substantial rights therein, including the rights to grant licenses, to exclude others, and to enforce and recover past damages for infringement of that patent.

28. Claim 1 of the '672 patent is reproduced below:

1. A method of determining an emergence of an ulcer on a given portion on at least one foot of a patient, the method comprising:
providing one or more processors;
providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors;
generating, using the plurality of temperature sensors, a plurality of discrete temperature data values after receipt of the at least one foot;
forming, by at least one of the one or more processors, at least one thermogram of a sole of each of the at least one foot of the patient from the discrete temperature data values, each thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole of one foot;
determining, by at least one of the one or more processors, whether the at least one thermogram presents at least one of a plurality of prescribed patterns;
said determining comprising comparing the at least one thermogram against a prior thermogram of the same foot; and
producing, by at least one of the one or more processors, output information indicating an emergence of an ulcer on a given portion on the at least one foot, said producing being a function of whether the at least one thermogram is determined to present the at least one prescribed pattern, said producing also being a function of the comparison, the prior thermogram showing non-ulcerated tissue at the given portion.

Exhibit 3 at 16:19-48.

29. On May 3, 2016, the USPTO issued U.S. Patent No. 9,326,723 (the "'723 patent"), titled "METHOD AND APPARATUS MONITORING FOOT INFLAMMATION." The '723 patent is valid and enforceable. A true and accurate copy of the '723 patent is attached hereto as Exhibit 4 and is incorporated herein by reference.

30. Podimetrics is the owner and assignee of all rights, title, and interest in and to the '723 patent and holds all substantial rights therein, including the rights to grant

licenses, to exclude others, and to enforce and recover past damages for infringement of that patent.

31. Claim 1 of the '723 patent is reproduced below:

1. A method of evaluating foot inflammation of at least one foot of a patient, each foot having a sole, the method comprising:

- providing one or more processors;
- generating, using at least one of the one or more processors and temperature data produced by at least one temperature detection modality, a first thermogram and a separate second thermogram of a sole of each of the at least one foot, each thermogram forming a spatially continuous data set of two-dimensional temperature values across a sole of each of the at least one foot, the first thermogram having first features, the second thermogram having second features;
- controlling at least one of the one or more processors to apply at least one transformation to one or both of the first and second thermograms to align the first features of the first thermogram with corresponding second features of the second thermogram;
- determining, by at least one of the one or more processors, at any thermogram location, if at least one of the thermograms presents one of a plurality of patterns indicative of foot inflammation; and
- producing, by at least one of the one or more processors, output information indicating a result of the determination of whether the thermograms present one of the plurality of patterns.

Exhibit 4 at 18:55-19:13.

32. Since the issuance of the Patents-in-Suit, Podometrics has virtually marked and continues to virtually mark its products in accordance with 35 U.S.C. § 287(a) via a publicly-available website (<https://www.podometrics.com/notices/patents/>), which identifies products, including SmartMat™, as covered by the Patents-in-Suit.

ORIGINS OF BLUEDROP

33. Upon information and belief, beginning in June 2012, Simon Kiersey was employed by Medtronic, Inc. (“Medtronic”) as an Associate R&D Engineer. During his time at Medtronic, Mr. Kiersey was (upon information and belief) involved in vascular

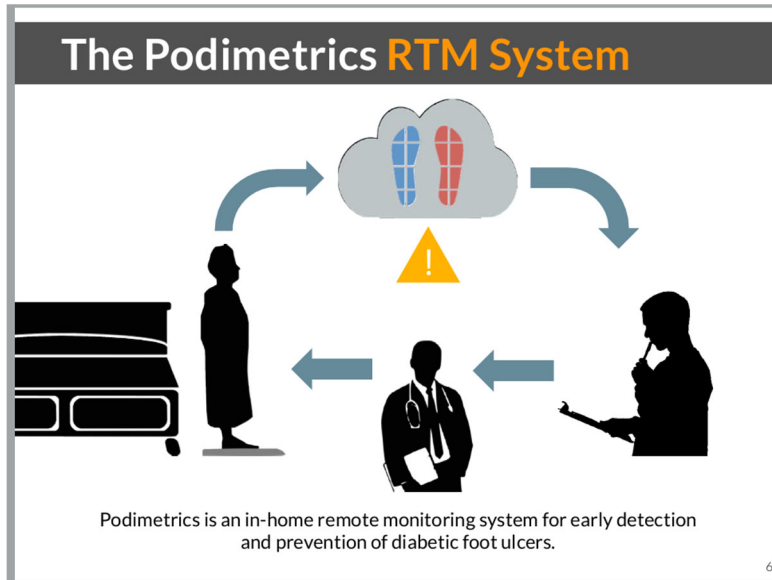
products and developed skills including clinical observations, needs identification and validation, market sizing, concept development, rapid prototyping, and developing a business case. Upon information and belief, Mr. Kiersey graduated from University College Dublin (in Ireland) in 2012 and Medtronic was his first job in the medical device field after receiving his degree.

34. Upon information and belief, beginning in August 2012, Chris Murphy was employed by Medtronic as an Associate Research and Development Engineer. During Mr. Murphy's time at Medtronic, he was (upon information and belief) involved in medical device design and development in the area of renal denervation, coronary, and structural heart devices. Upon information and belief, Medtronic was Mr. Murphy's first job after completing his studies at the University of Limerick (in Ireland).

35. In April 2015, Podimetrics entered into discussions with Medtronic as a possible partner for the product that became SmartMat™. Those discussions were conducted pursuant to a Mutual Non-Disclosure Agreement ("NDA"). As part of those discussions, and under that NDA, Podimetrics provided Medtronic with a slide deck that described Podimetrics' intellectual property, its business case, its commercialization plan, and other confidential information.


36. Among other things, that April 2015 slide deck included images that Podimetrics created to illustrate a "feedback loop" for remote patient monitoring that Podimetrics created to explain its "in-home remote monitoring system," namely data collection from a patient (via the device), analysis of that data in the "cloud" by Podimetrics, the clinic staff (*e.g.*, nurse or other staff) receiving certain alerts, potentially

passing that data to a doctor who may initiate preventive care (and who also prescribes the device to the patient initially), and instructing the patient on preventive care:



37. Podimetrics’ April 2015 confidential slide deck that it sent to Medtronic also contained a chart, which Podimetrics created, that summarized three clinical trials that used a prior art handheld temperature probe:

Thermometric detection



- Thermometry for the diabetic foot first emerged in the 1970s.¹⁻⁵
- Three RCTs have since examined the impact of identifying and off-loading patients with new plantar “hotspots” (temperature-guided avoidance therapy, TGAT) vs. standard prevention therapy on recurrence of ulceration in high risk individuals.⁶⁻⁸

Study	N	Follow-up period	Recurrence, Standard of Care	Recurrence, TGAT	Relative Reduction
Lavery 2004	85	6 months	15.9%	2.4%	85%
Lavery 2007	173	15 months	29.3%	8.5%	71%
Armstrong 2007	225	18 months	12.2%	4.7%	61%
Mean:					70%

1. Bergthold, Rehab Service Admin 1977. 2. Bergthold et al Arch Phys Med Rehabil 1975. 3. Bergthold HT, Phys Ther. 1979.
4. Beach RB, et al. Phys Ther. 1979. 5. Manley et al. Arch Phys Med Rehabil. 1980. 6. Lavery et al Diabetes Care. 2004.
7. Lavery et al. Diabetes Care 2007. 8. Armstrong et al. Am J Med. 2007.

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38. That slide deck also described Podimetrics’ “commercial plan” for its device (different versions), its “go to market” strategy, the funding Podimetrics was seeking, and

“early learnings” from pre-commercial launch sales. It also identified several patent applications it had filed, which became one or more of the Patents-in-Suit.

39. Upon information and belief, Mr. Kersey and/or Mr. Murphy reviewed or had access to Podometrics’ confidential information, including the aforementioned April 2015 slide deck that Podometrics provided to Medtronic under an NDA.

40. Upon information and belief, Messrs. Kersey and Murphy left Medtronic and founded BlueDrop in April 2015.

41. Upon information and belief, BlueDrop, at least by 2017, created and publicly used a slide deck that included ideas that appear to be drawn or taken from Podometrics’ 2015 slide deck it provided to Medtronic, including a similar “feedback loop” and summary of clinical research and data:



BLUEDROP MEDICAL

CLINICAL RESEARCH


Temperature Monitoring of the Diabetic Foot

Temperature monitoring of the sole of the foot has been proven to reduce the rate of ulceration by 70%.

This has been proven through 3 randomised controlled trials in the USA. Total of 483 subjects. Studies used a handheld temperature probe (TempTouch, pictured to the right)

70%

Reduction in the rate of ulceration¹²



Clinical trial results					
Year	Investigator	Location	Patients	Control ulceration	Study ulceration
2004	Lavery ¹¹	USA	85	20%	2%
2007	Lavery ¹²	USA	173	29.3%	8.5%
2007	Armstrong ¹³	USA	225	12%	4.7%

- Temperature measurement is taken at 6 points on each foot and recorded in log book
- Temperature between opposite points is analysed
- A temperature difference of 2.2°C (4°F) indicates inflammation and hence the emergence of an ulcer

© Confidential property of Bluedrop Medical. Not to be shared without written consent.

42. Beginning in or about 2017, Podimetrics also had discussions with KCI/Acelity as another possible partner for the product that eventually became SmartMat™. As part of those discussions, Podimetrics provided KCI/Acelity with a confidential slide deck in February 2019. That slide deck is similar to the one that Podimetrics previously provided to Medtronic (in 2015).

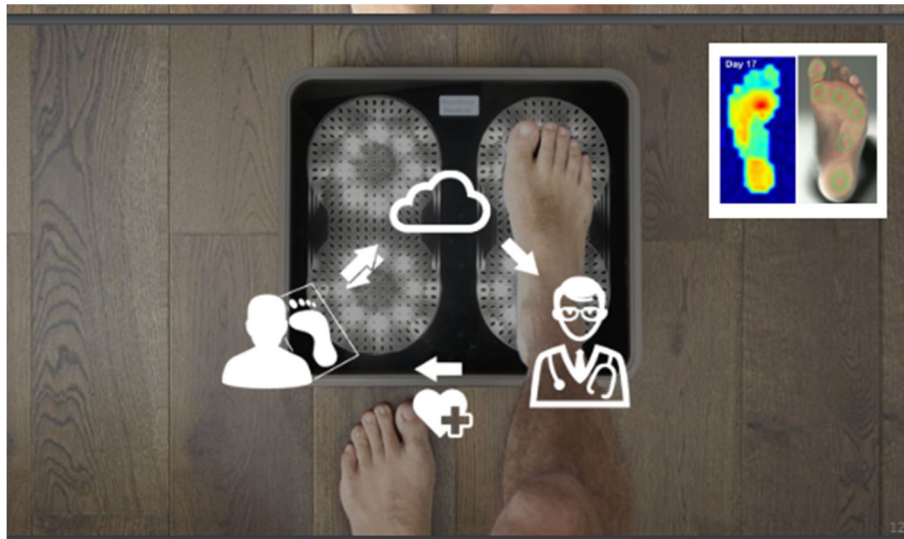
43. Mr. Sandroussi worked at KCI/Acelity and, upon information and belief, was involved in the discussions between Podimetrics and KCI/Acelity. For example, in February 2019, he received an email from Podimetrics that contained the aforementioned confidential slide deck. Subsequently, Mr. Sandroussi joined Bluedrop and became its Chief Commercial Officer.

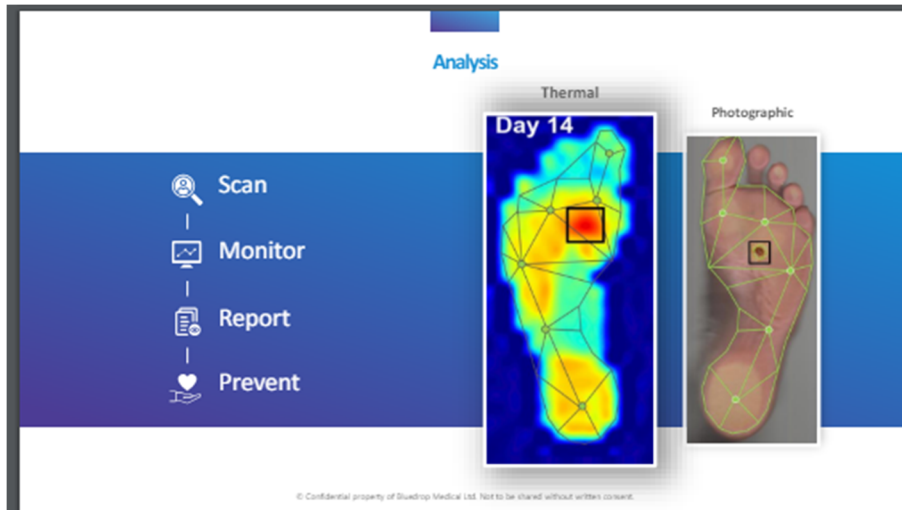
44. In 2018, Podimetrics had several conversations and exchanged emails with Dr. Scott. At that time, upon information and belief, Dr. Scott was associated with Baylor Scott & White Health (a large health care system in Texas). During those interactions, Podimetrics provided Dr. Scott with information about the SmartMat™ and confidential aspects of Podimetrics' business model and market approach. Subsequently, Dr. Scott

joined Bluedrop and became its Medical Director.

45. Upon information and belief, Bluedrop, in 2020, presented at the Women in STEM Summit Ireland, and showed a slide deck. Although that slide deck states, on its face, that it is Bluedrop’s “confidential property,” is it currently publicly available, at least at: <https://womeninstem.ie/wp-content/uploads/2020/02/Chris-Murphy.pdf> (“2020 Bluedrop Presentation”) (visited June 24, 2024). That 2020 slide deck uses graphics, ideas, and information that were in Podimetrics’ 2015 Medtronic confidential slide deck and in Podimetrics’ 2019 KCI/Acelity confidential slide deck.

46. The Bluedrop 2020 presentation also contains images of Bluedrop’s remote patient monitoring (“RPM”) device and determination of temperature in 6 different areas of a foot to detect “hot spots” – features that are still part of Bluedrop’s RPM device:





See 2020 Bluedrop Presentation at 12, 15.

BLUEDROP'S INFRINGEMENT OF THE PATENTS-IN-SUIT

47. On March 31, 2022, Podimetrics sent Bluedrop a letter. In it, Podimetrics identified the Patents-in-Suit, stated its understanding that it was Bluedrop's intent to offer an RPM device for the prevention of diabetic foot ulcers, contended (based on public information) that Bluedrop's then-in-development RPM device would (if sold or offered for sale in the United States) infringe the Patents-in-Suit, and stated that Podimetrics would continue to evaluate Bluedrop's RPM device if it was sold or offered for sale in the United States.

48. On July 4, 2022, Bluedrop responded to Podimetrics' letter with an email. That email, in full, states: "Thank you for your email and letter dated March 31, 2022 regarding your patents. We have reviewed them and it appears they require a particular type of thermogram. While some of our older publicly available material does show a display of thermal data, we do not plan for our US products to include such a display, or any other thermal foot display. Based on this, please let us know if you still believe there

are any patent issues.”

49. On August 8, 2022, Podimetrics responded to Bluedrop’s email via a letter. In it, Podimetrics stated that Bluedrop “only identified the alleged lack of ‘thermogram’ limitations as the supposed basis for distinguishing Bluedrop[’s] RPM device from Podimetrics’ U.S. patents.” Accordingly, Podimetrics informed Bluedrop that “[w]e therefore understand your email to confirm that Bluedrop[’s] RPM device meets all the other limitations of the claims of Podimetrics’ U.S. patents. If this is incorrect, please provide evidence so that we can evaluate [Bluedrop’s] contentions as to other claim limitation(s).”

50. The August 8, 2022 letter also stated that Bluedrop’s “view of the ‘thermogram’ limitations in Podimetrics’ U.S. patents is incorrect....There is no requirement in any of the independent claims of Podimetrics’ U.S. patents for a thermogram ‘display,’ a ‘display of thermal data,’ or ‘any other thermal foot display.’ If you disagree, please identify where, in each of the independent claims of Podimetrics’ U.S. patents, you believe such a requirement is present.”

51. The August 8, 2022 letter invited Bluedrop to provide additional information about its RPM device, particularly because the terse nature of Bluedrop’s email impaired Podimetrics’ ability to evaluate Bluedrop’s assertions. Podimetrics also stated that it would take all necessary actions to protect its rights and its U.S. patents, including if Bluedrop’s RPM device was sold or offered for sale in the United States.

52. Podimetrics never received a response to its August 2022 letter, nor did Bluedrop provide any information or basis for the statements it made in its July 4, 2022

email or in response to Podimetrics' pointed requests.

53. Upon information and belief, in 2024, Bluedrop registered with the FDA to begin selling, offering for sale, and importing in the United States an RPM device called the Bluedrop OneStep Foot Scanner and/or the Bluedrop Delta Foot Scanner, which requires access to an accompanying service that appears to be called the EveryStep Monitoring Service (individually and collectively, the "Bluedrop Foot Scanner").

54. The Bluedrop Foot Scanner is a device that is akin to a scale that, among other things, uses temperature monitoring to detect areas of the foot that are at risk of presenting with a diabetic foot ulcer. The device captures temperature across each foot with every scan to identify "hot spots." That information is sent to Bluedrop, who then engages directly with the patient's health care provider and patient to notify and advise on steps to alleviate "risk areas on the feet."



It starts with one simple step.



The OneStep Foot Scanner is designed with people in mind. It resembles a common home weighing scale and from a patient point of view, works the same. They simply stand on the scanner for approximately 30 seconds and it captures and transmits foot temperature data + hi-resolution images of the feet for remote analysis.



Our EveryStep Monitoring Service then analyzes the temperature and image data to identify risk areas on the feet, and engages with patients and prescribers as needed.

See <https://bluedropmedical.com/> (visited June 24, 2024)

INTENDED USE

The Bluedrop Monitoring System is intended for use by persons over the age of 18 years who are at risk of inflammation related foot conditions such as diabetic foot ulcers.

The Bluedrop Monitoring System (BMS) is comprised of the Delta Foot Scanner (DFS) device and its accompanying Sentinel Review Interface (SRI) software. The BMS allows the condition of the soles of the feet to be remotely monitored for thermal and visual signs of inflammation, both of which may signal the onset of certain conditions, such as diabetic foot ulcers.

Under the direction of a health care professional, the DFS should be used on a daily basis by the patient, in their place of residence. By placing the feet on the indicated surface from a standing or sitting position, it will measure the dermal temperature and record visual images of the soles of the feet. When used from a standing position the DFS will also record the patient's weight.

The SRI software will provide the data recorded by the device to a health care professional, to analyze the patient's results. The health care professional will use this data to determine if further evaluation and treatment are necessary for the patient. They will continue to monitor the images and temperature data for any persistent localized inflammation or skin changes on a regular basis and communicate with their patient as necessary.

Description of the Device

The DFS device includes sensors to collect visual and thermal information over the soles of the feet and transmit that data wirelessly to a remote server for evaluation.

The device includes a top panel on which there are an array of temperature sensors. Beneath this panel is an array of light sources and image sensors.

The user places the soles of their dry feet on the top panel of the device either by standing on the device or from a seated position. A scan is then taken by the device and is transmitted securely via the internet where it can be accessed by the user's healthcare provider for monitoring and analysis of the patient.

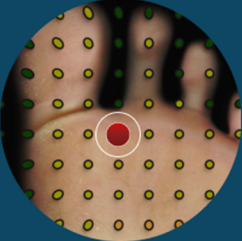
When the device is used from a standing position the user's weight is also recorded and displayed to the user.

See Bluedrop Delta Foot Scanner User Guide at 2, 4 (available at <https://bluedropmedical.com/wp-content/uploads/2024/02/Bluedrop-User-Guide.pdf>)

(visited June 24, 2024).

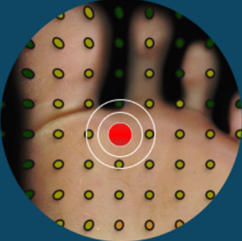
Temperature Analysis

Several studies support the use of temperature monitoring to detect areas of the foot that are at risk of presenting with a diabetic foot ulcer. In fact, evidence suggests that 70% of ulcers may be avoided by using temperature monitoring to identify “hot spots” on the foot. Our system captures temperature across over **100** points on each foot with every scan to identify hot spots. We then engage directly with patients to notify and advise on steps to alleviate risk.



Singe Scan Hot Spot

In these cases, we review the visual images to ensure a wound isn't present. If no wound or other issue is detected visually, we will continue to monitor.



Trending Hot Spot

In these cases, we speak to the patients to learn more about their activity that day. We advise on general ways to alleviate pressure on their feet and direct to follow any foot care instructions from their doctor. If the trend persists beyond 3 consecutive scans, we will alert the prescriber.

See <https://bluedropmedical.com/new-providers/> (visited June 24, 2024).

55. According to information published on the NIH’s Access GUDID website for the Bluedrop Foot Scanner:

⊖ GMDN [2]

GMDN® Term Code, Names and Definitions (*[Terms of Use](#)): GMDN® is a registered trademark of The GMDN Agency. All rights reserved. Used under licence from The GMDN Agency Ltd.

GMDN Term Code	GMDN Term Name	GMDN Term Definition	GMDN Term Status [2]	Implantable?
36731	Thermographic camera	A camera intended to measure and display differences in temperature, usually shown by colour differences, in humans or objects. Differences in temperature may be used for examination and diagnosis applications (e.g., in skin conditions, vascular disorders, or breast malignancies). This device may be stand-alone or part of a thermographic system.	Active	false

See Access GUDID, Bluedrop Medical (05391536710002) (available at <https://accessgudid.nlm.nih.gov/devices/05391536710002>) (visited June 24, 2024).

56. Bluedrop instructs patients on how to set-up and use the Bluedrop Foot Scanner. *See, e.g.*, Bluedrop Delta Foot Scanner User Guide; Bluedrop Quick Start Guide (available at <https://bluedropmedical.com/wp-content/uploads/2024/02/Bluedrop-Quick-Start-Guide.pdf>) (visited June 24, 2024); Bluedrop Patient Flyer (available at <https://bluedropmedical.com/wp-content/uploads/2024/02/BD-Patient-Flyer-V01.pdf>) (visited June 24, 2024).

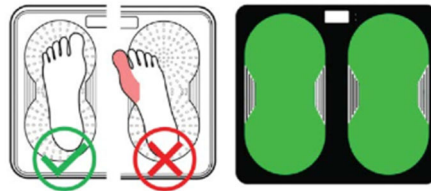
57. Among other things, Bluedrop instructs patients using the Bluedrop Foot Scanner to place their feet entirely within a large area indicated on the device (*e.g.*, area indicated in green, below), but, so long as the feet are within that large area, the positioning and orientation of each foot does not need be identical:

Taking a Scan Step onto the scanner barefoot

 The maximum allowable weight is 330lbs (150kg).

Now that your scanner is set up, to use it you simply need to stand on it barefoot. You will not need to set it up every time.

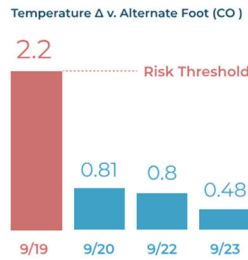
- We recommend you to use the scanner every day, in the morning or as instructed by your healthcare provider
- The scanner works in the same way as a normal weight scales. You can step on the scanner when the screen is blank. The scanner will automatically detect your weight and start a scan.
- You need to ensure that each foot is placed in the sensing area (highlighted in green below). If your foot is not in this region, the scanner will not be able to take a scan of your feet.



Bluedrop Delta Foot Scanner User Guide at 12.

58. According to Bluedrop’s website, the Bluedrop Foot Scanner uses “proprietary sensor technology” to enable “capture of accurate temperature data” to create

a “holistic monitoring approach” with a 2.2 °C “risk threshold” for a “hot spot” including:



“Hot Spot” With Superficial Skin Lesion

Outcome: Coaching to patient and monitoring by Bluedrop through healing without need to utilize clinical resources.

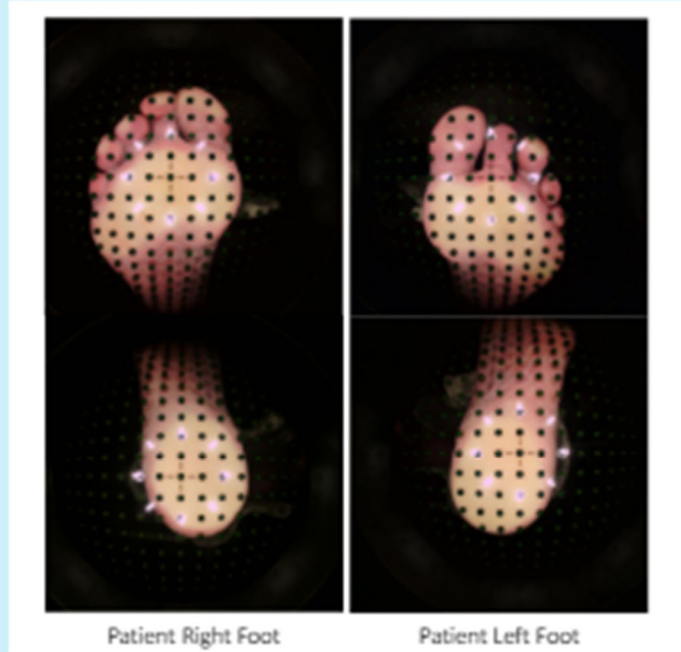
See 2023 Bluedrop Provider Brochure (available at <https://bluedropmedical.com/wp-content/uploads/2024/02/BD-MD-Flyer-V01.pdf>) (visited June 24, 2024).

59. On its website, Bluedrop describes a study performed using the Bluedrop Foot Scanner, which states that the device determines temperatures at six different areas of the sole of each foot and compares them to determine “hot spots”:

- Remote temperature monitoring (RTM) has been proposed to reduce the high rates of recurrence. Six points are assessed on each foot and compared. A hot spot is defined as a 2.2°C temperature difference between similar points on opposite feet. (3, 4, 5). See Figure 1 for dashboard view of the software presenting temperature and visual information.

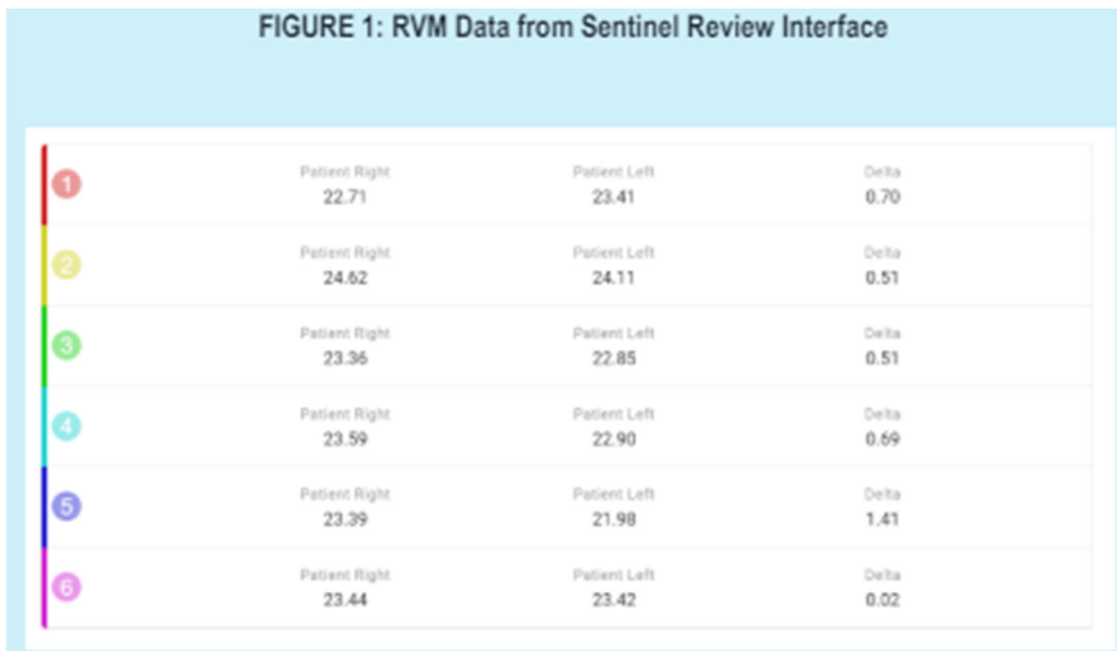
...

Bluedrop Medical have developed the Delta Foot Scanner (DFS) – see Figure 3 -, which allows for combined thermal data and visual images of the feet to be taken in an easy to use device. The device is designed to look and behave like a standard home weight scale and takes 30 seconds to use per day.



Black dots = patented temperature sensors

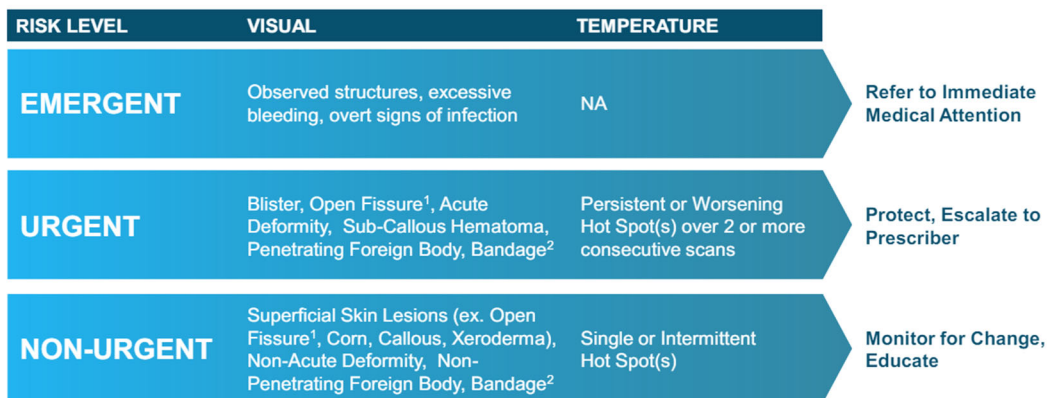
FIGURE 1: RVM Data from Sentinel Review Interface



See 2023 Bluedrop Poster (available at <https://bluedropmedical.com/wp-content/uploads/2023/06/ISDF-2023-Poster-Final-080523.pdf> (visited June 24, 2024).

60. A “hot spot” determined by the Bluedrop Foot Scanner at one (or more) of the six areas on a foot may be indicative of the emergence of a pre-ulcer or the progression of a known pre-ulcer. For example, according to Bluetop’s materials, the Bluedrop Foot Scanner determines “urgent” and “non-urgent” “risk criteria” based on “hot spots”:

Bluedrop Model Considers Risk Criteria for Appropriate Action



See Bluedrop Engagement Guide at 2 (available at <https://bluedropmedical.com/wp->

content/uploads/2024/02/Bluedrop-Medical-Engagement-Guide_13Feb2024.pdf (visited June 24, 2024).

FIRST CLAIM FOR RELIEF
(Willful Infringement of United States Patent No. 9,095,305)

61. The allegations stated in preceding paragraphs are incorporated by reference as though fully set forth herein.

62. Podimetrics is the sole owner of the '305 patent.

63. Bluedrop makes, uses, sells, offers to sell, and/or imports the Bluedrop Foot Scanner in the United States.

64. The Bluedrop Foot Scanner performs all the elements of, at least, Claim 1 of the '305 patent and/or Bluedrop instructs and/or induces customers to use the Bluedrop Foot Scanner to perform the method of, at least, Claim 1.

65. To the extent the preamble of Claim 1 of the '305 patent is found to be limiting, the Bluedrop Foot Scanner, including as shown above, determines the emergence of a pre-ulcer or progression of a known pre-ulcer on at least one foot of a patient. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet the preamble (to the extent the Court determines the preamble is a limitation).

66. Claim 1 of the '305 patent requires "providing one or more processors." The Bluedrop Foot Scanner meets this limitation, including as shown above. The device "processes" data it receives, which necessarily requires one or more processors. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any

argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

67. Claim 1 of the '305 patent requires “providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors.” The Bluedrop Foot Scanner meets this limitation, including as shown above. It is a scale-like device that has an “array” of temperature sensors. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

68. Claim 1 of the '305 patent requires “generating, using the plurality of temperature sensors, a plurality of discrete temperature data values after receipt of the at least one foot.” The Bluedrop Foot Scanner meets this limitation, including as shown above. It has an “array” of temperature sensors, that collect “thermal information” “over the soles [sic] of the foot.” Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

69. Claim 1 of the '305 patent requires “forming, by at least one of the processors, at least one thermogram of the sole of each of the at least one foot from the discrete temperature data values, the thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole.”

70. The specification of the '305 patent, which does not limit the scope of the claimed invention, contains the following:

25 In simple terms, as known by those in the art, a thermogram
 is a data record made by a thermograph, or a visual display of
 that data record. A thermograph simply is an instrument that
 records temperatures (i.e., the platform 16). As applied to
 illustrative embodiments, a thermograph measures tempera-
 30 tures and generates a thermogram, which is data, or a visual
 representation of that data, of the continuous two-dimen-
 sional temperature data across some physical region, such as
 a foot 10. Accordingly, unlike an isothermal representation of
 temperature data, a thermogram provides a complete, con-
 35 tinuous data set/map of the temperatures across an entire
 two-dimensional region/geography. More specifically, in
 various embodiments, a thermogram shows (within accepted
 tolerances) substantially complete and continuous two-di-
 mensional spatial temperature variations and gradients across
 40 portions of the sole of (at least) a single foot 10, or across the
 entire sole of the single foot 10.

Exhibit 1 at 10:25-41.

71. The Bluedrop Foot Scanner meets this limitation, including as shown above. It receives temperature data from its “array of temperature sensors” and uses that data to create and compare the temperatures of six areas of each foot to determine the presence of “hot spots.” Upon information and belief, these determined hot spots may be between two “temperature sensors.” In addition, the Bluedrop Foot Scanner includes a “camera intended to measure and display differences in temperature, usually shown by colour [sic] differences.”

72. Details of how, precisely, temperature data is used in the Bluedrop Foot Scanner are, upon information and belief, described and implemented by non-public aspects of the Bluedrop Foot Scanner’s software. Upon information and belief, discovery will yield additional information about how the Bluedrop Foot Scanner meets this claim limitation. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

73. Claim 1 of the '305 patent requires “determining, by at least one of the processors, at any location within the at least one thermogram of the sole, whether the thermogram presents at least one of a plurality of prescribed patterns.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The Bluedrop Foot Scanner receives temperature data from its “array of temperature sensors,” uses that data to create a thermogram, and compares six areas of each foot to determine a “hot spot.” Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

74. Claim 1 of the '305 patent requires “producing, by at least one of the processors, output information indicating an emergence of a pre-ulcer or progression of a known pre-ulcer in the at least one foot, producing being a function of whether the thermogram is determined to present the at least one pattern.” The Bluedrop Foot Scanner meets this limitation, including as show above. The device uses a thermogram to determine the presence of “hot spots” which are indicative of an emergence of a pre-ulcer or progression of a known pre-ulcer. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

75. By at least March 31, 2022, Bluedrop had actual knowledge of the '305 patent. At least by that date, Bluedrop’s actions were – and continue to be – willful and intentional, including under the standard the Supreme Court articulated in *Halo*

Electronics, Inc. v. Pulse Electronics, Inc.

76. Upon information and belief, as of the date of Podimetrics' March 31, 2022 letter, Bluedrop had not yet sold, offered for sale, or imported the Bluedrop Foot Scanner in the United States. Notwithstanding Podimetrics' March 31, 2022 letter, Bluedrop subsequently actively, knowingly, and intentionally began providing the Bluedrop Foot Scanner and instructions to its U.S. customers and users on how to set it up and to use it in an infringing manner. The Bluedrop Foot Scanner is not a staple article of commerce suitable for non-infringing uses.

77. By making, using, testing, offering for sale, selling, and/or importing the Bluedrop Foot Scanner, and by disseminating product descriptions and operating manuals, and by providing instructions to end-users on how to configure and use the Bluedrop Foot Scanner, Bluedrop has infringed and is infringing the '305 patent, including at least Claim 1, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) – literally or under the doctrine of equivalents.

78. Podimetrics has been damaged by Bluedrop's infringement of the '305 patent and is suffering and will continue to suffer irreparable harm and damage as a result of this infringement unless such infringement is enjoined by this Court.

SECOND CLAIM FOR RELIEF
(Willful Infringement of United States Patent No. 9,259,178)

79. The allegations stated in preceding paragraphs are incorporated by reference as though fully set forth herein.

80. Podimetrics is the sole owner of the '178 patent.

81. Bluedrop makes, uses, sells, offers to sell, and/or imports the Bluedrop Foot Scanner in the United States.

82. The Bluedrop Foot Scanner performs all the elements of, at least, Claim 1 of the '178 patent and/or Bluedrop instructs and/or induces customers to use the Bluedrop Foot Scanner perform the claimed method.

83. To the extent the preamble of Claim 1 of the '178 patent is found to be limiting, the Bluedrop Foot Scanner, including as shown above, determines risk of an ulcer emerging on at least one foot of a patient. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet the preamble (to the extent the Court determines the preamble is a limitation).

84. Claim 1 of the '178 patent requires "providing one or more processors." The Bluedrop Foot Scanner meets this limitation, including as shown above. The device "processes" data it receives, which necessarily requires one or more processors. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

85. Claim 1 of the '178 patent requires "providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors." The Bluedrop Foot Scanner meets this limitation, including as shown above. It is a scale-like device that has an "array" of temperature sensors. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

86. Claim 1 of the '178 patents requires “forming, by at least one of the one or more processors, at least one thermogram of a sole of each of the at least one foot from the discrete temperature data values, the at least one thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole of each of the at least one foot.”

87. The specification of the '178 patent, which does not limit the scope of the claimed invention, contains the following:

15 In simple terms, as known by those in the art, a thermogram
is a data record made by a thermograph, or a visual display of
that data record. A thermograph simply is an instrument that
records temperatures (i.e., the platform 16). As applied to
illustrative embodiments, a thermograph measures tempera-
20 tures and generates a thermogram, which is data, or a visual
representation of that data, of the continuous two-dimen-
sional temperature data across some physical region, such as
a foot 10. Accordingly, unlike an isothermal representation of
temperature data, a thermogram provides a complete, con-
25 tinuous data set/map of the temperatures across an entire
two-dimensional region/geography. More specifically, in
various embodiments, a thermogram shows (within accepted
tolerances) substantially complete and continuous two-di-
mensional spatial temperature variations and gradients across
30 portions of the sole of (at least) a single foot 10, or across the
entire sole of the single foot 10.

Exhibit 2 at 10:15-31.

88. The Bluedrop Foot Scanner meets this limitation, including as shown above. It receives temperature data from its “array of temperature sensors” and uses that data to create and compare the temperatures of six areas of each foot to determine the presence of “hot spots. Upon information and belief, these determined hot spots may be between two “temperature sensors.” In addition, the Bluedrop Foot Scanner includes a “camera intended to measure and display differences in temperature, usually shown by colour [sic] differences.”

89. Details of how, precisely, the temperature data is used in the Bluedrop Foot Scanner are, upon information and belief, described and implemented by non-public aspects of the Bluedrop Foot Scanner’s software. Upon information and belief, discovery will yield additional information about how the Bluedrop Foot Scanner meets this claim limitation. Further, despite Podometrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

90. Claim 1 of the ’178 patent requires “determining, by at least one of the processors, at any location within the at least one thermogram of the sole of the at least one foot, whether the at least one thermogram presents at least one of a plurality of prescribed patterns.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The Bluedrop Foot Scanner receives temperature data from its “array of temperature sensors,” uses that data to create a thermogram, and compares six areas of each foot to determine a “hot spot.” Further, despite Podometrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

91. Claim 1 of the ’178 patent requires “producing, by at least one or more processors, output information indicating a risk of an ulcer emerging on the at least one foot, said producing being a function of whether the at least one thermogram is determined to present the at least one of the plurality of prescribed patterns.” The Bluedrop Foot Scanner meets this limitation, including as show above. The device uses a thermogram to

determine the presence of “hot spots” which are indicative of an emergence of an ulcer on a foot. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

92. By at least March 31, 2022, Bluedrop had actual knowledge of the ’178 patent. At least by that date, Bluedrop’s actions were – and continue to be – willful and intentional, including under the standard the Supreme Court articulated in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*

93. Upon information and belief, as of the date of Podimetrics’ March 31, 2022 letter Bluedrop had not yet sold, offered for sale, or imported the Bluedrop Foot Scanner in the United States. Notwithstanding Podimetrics’ March 31, 2022 letter, Bluedrop subsequently actively, knowingly, and intentionally began providing the Bluedrop Foot Scanner and instructions to its U.S. customers and users on how to set it up and to use it in an infringing manner. The Bluedrop Foot Scanner is not a staple article of commerce suitable for non-infringing uses.

94. By making, using, testing, offering for sale, selling, and/or importing the Bluedrop Foot Scanner, and by disseminating product descriptions and operating manuals, and by providing instructions to end-users on how to configure and use the Bluedrop Foot Scanner, Bluedrop has infringed and is infringing the ’178 patent, including at least Claim 1, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) – literally or under the doctrine of equivalents.

95. Podimetrics has been damaged by Bluedrop’s infringement of the ’178 patent

and is suffering and will continue to suffer irreparable harm and damage as a result of this infringement unless such infringement is enjoined by this Court.

THIRD CLAIM FOR RELIEF
(Willful Infringement of United States Patent No. 9,271,672)

96. The allegations stated in preceding paragraphs are incorporated by reference as though fully set forth herein.

97. Podimetrics is the sole owner of the '672 patent.

98. Bluedrop makes, uses, sells, offers to sell, and/or imports the Bluedrop Foot Scanner in the United States.

99. The Bluedrop Foot Scanner performs all the elements of, at least, Claim 1 of the '672 patent and/or Bluedrop instructs and/or induces customers to use the Bluedrop Foot Scanner perform the claimed method.

100. To the extent the preamble of Claim 1 of the '672 patent is found to be limiting, the Bluedrop Foot Scanner, including as shown above, determines the emergence of an ulcer on least one foot of a patient. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet the preamble (to the extent the Court determines the preamble is a limitation).

101. Claim 1 of the '672 patent requires "providing one or more processors." The Bluedrop Foot Scanner meets this limitation, including as shown above. The device "processes" data it receives, which necessarily requires one or more processors. Further, despite Podimetrics' request (in its August 8, 2022 letter), Bluedrop never provided any

argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

102. Claim 1 of the '672 patent requires “providing an open platform for receiving at least one foot, the open platform having a plurality of temperature sensors.” The Bluedrop Foot Scanner meets this limitation, including as shown above. It is a scale-like device that has an “array” of temperature sensors. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

103. Claim 1 of the '672 patent requires “generating, using a plurality of temperature sensors, a plurality of discrete temperature values after receipt of the at last [sic] one foot.” The Bluedrop Foot Scanner meets this limitation, including as shown above. It has an “array” of temperature sensors, which collect “thermal information” “over the soles of the foot.” Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

104. Claim 1 of the '672 patent requires “forming, by at least one of the one or more processors, at least one thermogram of a sole of each of the at least one foot of the patient from the discrete temperature data values, each thermogram comprising a spatially continuous data set of two-dimensional temperature values across the sole of one foot.”

105. The specification of the '672 patent, which does not limit the scope of the claimed invention, contains the following:

In simple terms, as known by those in the art, a thermogram
 5 is a data record made by a thermograph, or a visual display of
 that data record. A thermograph simply is an instrument that
 records temperatures (i.e., the platform 16). As applied to
 illustrative embodiments, a thermograph measures tempera-
 10 tures and generates a thermogram, which is data, or a visual
 representation of that data, of the continuous two-dimen-
 sional temperature data across some physical region, such as
 a foot 10. Accordingly, unlike an isothermal representation of
 temperature data, a thermogram provides a complete, con-
 15 tinuous data set/map of the temperatures across an entire
 two-dimensional region/geography. More specifically, in
 various embodiments, a thermogram shows (within accepted
 tolerances) substantially complete and continuous two-di-
 20 mensional spatial temperature variations and gradients across
 portions of the sole of (at least) a single foot 10, or across the
 entire sole of the single foot 10.

Exhibit 3 at 10:4-20.

106. The Bluedrop Foot Scanner meets this limitation, including as shown above. It receives temperature data from its “array of temperature sensors” and uses that data to create and compare the temperatures of six areas of each foot to determine the presence of “hot spots.” Upon information and belief, these determined hot spots may be between two “temperature sensors.” In addition, the Bluedrop Foot Scanner includes a “camera intended to measure and display differences in temperature, usually shown by colour [sic] differences.”

107. Details of how, precisely, the temperature data is used in the Bluedrop Foot Scanner are, upon information and belief, described and implemented by non-public aspects of the Bluedrop Foot Scanner’s software. Upon information and belief, discovery will yield additional information about how the Bluedrop Foot Scanner meets this claim limitation. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

108. Claim 1 of the '672 patent requires “determining, by at least one or more of the processors, whether the at least one thermogram presents at least one of a plurality of prescribed patterns.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The Bluedrop Foot Scanner receives temperature data from its “array of temperature sensors,” uses that data to create a thermogram, and compares six areas of each foot to determine a “hot spot.” Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

109. Claim 1 of the '672 patent requires “said determining comprising comparing the at least one thermogram against a prior thermogram of the same foot.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The device uses a thermogram to determine the presence of “hot spots” each time the device scans a foot. The device determines, among other things, that a “hot spot” is “non-urgent” if it is present in a scan, but was not present in the immediately prior scan, or “urgent” if it is present in two or more consecutive scans. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

110. Claim 1 of the '672 patent requires “producing, by at least one of the processors, output information indicating an emergence of an ulcer on a given portion on the at least one foot, said producing being a function of whether the at least one thermogram

is determined to present the at least one prescribed pattern, said producing also being a function of the comparison, the prior thermogram showing non-ulcerated tissue at the given portion.”

111. The Bluedrop Foot Scanner meets this limitation, including as shown above. The device uses a thermogram to determine the presence of “hot spots” each time the device scans a foot. The device determines the emergence of an ulcer based, at least in part, on the worsening (or increased temperature) at a “hot spot” over time. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

112. By at least March 31, 2022, Bluedrop had actual knowledge of the ’672 patent. At least by that date, Bluedrop’s actions were – and continue to be – willful and intentional, including under the standard the Supreme Court articulated in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*

113. Upon information and belief, as of the date of Podimetrics’ March 31, 2022 letter, Bluedrop had not yet sold, offered for sale, or imported the Bluedrop Foot Scanner in the United States. Notwithstanding Podimetrics’ March 31, 2022 letter, Bluedrop subsequently actively, knowingly, and intentionally began providing the Bluedrop Foot Scanner and instructions to its U.S. customers and users on how to set it up and to use it in an infringing manner. The Bluedrop Foot Scanner is not a staple article of commerce suitable for non-infringing uses.

114. By making, using, testing, offering for sale, selling, and/or importing the

Bluedrop Foot Scanner, and by disseminating product descriptions and operating manuals, and by providing instructions to end-users on how to configure and use the Bluedrop Foot Scanner, Bluedrop has infringed and is infringing the '672 patent, including at least Claim 1, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) – literally or under the doctrine of equivalents.

115. Podimetrics has been damaged by Bluedrop's infringement of the '672 patent and is suffering and will continue to suffer irreparable harm and damage as a result of this infringement unless such infringement is enjoined by this Court.

FOURTH CLAIM FOR RELIEF
(Willful Infringement of United States Patent No. 9,326,723)

116. The allegations stated in preceding paragraphs are incorporated by reference as though fully set forth herein.

117. Podimetrics is the sole owner of the '723 patent.

118. Bluedrop makes, uses, sells, offers to sell, and/or imports the Bluedrop Foot Scanner in the United States.

119. The Bluedrop Foot Scanner performs all the elements of, at least, Claim 1 of the '723 patent and/or Bluedrop instructs and/or induces customers to use the Bluedrop Foot Scanner perform the claimed method.

120. To the extent the preamble of Claim 1 of the '723 patent is found to be limiting, the Bluedrop Foot Scanner, including as shown above, evaluates foot inflammation (*e.g.*, a foot ulcer) in a foot of a patient (which has a sole).

121. Claim 1 of the '723 patent requires “providing one or more processors.” The

Bluedrop Foot Scanner meets this limitation, including as shown above. The device “processes” data it receives, which necessarily requires one or more processors. Further, despite Podometrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument as to why it believes the Bluedrop Foot Scanner does not meet this limitation.

122. Claim 1 of the ’723 patent requires “generating, using at least one of the one or more processors and temperature data produced by at least one temperature detection modality, a first thermogram and a separate second thermogram of a sole of each of the at least one foot, each thermogram forming a spatially continuous data set of two-dimensional temperature values across a sole of each of the at least one foot, the first thermogram having first features, the second thermogram having second features.”

123. The specification of the ’723 patent, , which does not limit the scope of the claimed invention, contains the following:

In simple terms, as known by those in the art, a thermogram is a data record made by a thermograph, or a visual display of that data record. A thermograph simply is an instrument that records temperatures (i.e., the platform **16**). As applied to illustrative embodiments, a thermograph measures temperatures and generates a thermogram, which is data, or a visual representation of that data, of the spatially-continuous two-dimensional temperature data across some physical region, such as a foot **10**. Accordingly, unlike an isothermal representation of temperature data, a thermogram provides a complete, continuous data set/map of the temperatures across an entire two-dimensional region/geography. More specifically, in various embodiments, a thermogram shows (within accepted tolerances) substantially complete and continuous two-dimensional spatial temperature variations and gradients across portions of the sole of (at least) a single foot **10**, or across the entire sole of the single foot **10**.

Exhibit 4 at 9:33-49.

124. The Bluedrop Foot Scanner meets this limitation, including as shown above. It receives temperature data from its “array of temperature sensors” and uses that data to

create and compare the temperatures of six areas of each foot to determine the presence of “hot spots.” Upon information and belief, these determined hot spots may be between two “temperature sensors.” In addition, the Bluedrop Foot Scanner includes a “camera intended to measure and display differences in temperature, usually shown by colour [sic] differences.” Further, if a patient puts both feet on the device at the time a scan is performed by the device, the device generates a first and a second thermogram (one for each foot).

125. Details of how, precisely, the temperature data is used in the Bluedrop Foot Scanner are, upon information and belief, described and implemented by non-public aspects of the Bluedrop Foot Scanner’s software. Upon information and belief, discovery will yield additional information about how the Bluedrop Foot Scanner meets this claim limitation. Further, despite Podometrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

126. Claim 1 of the ’723 patent requires “controlling at least one of the one or more processors to apply at least one transformation to one or both of the first and second thermograms to align the first features of the first thermogram with corresponding second features of the second thermogram.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The device compares six areas of one foot to the corresponding six areas of the second foot. Further, as shown above, the device shows each foot aligned the same way (the patient’s feet need not be aligned identically when the patient steps on the device – so long as they are within the proscribed area, which is likely larger than the

patient's actual feet). Therefore, upon information and belief, the device performs a transformation so as to be able to compare the same six areas of each foot.

127. Details of how, precisely, the Bluedrop Foot Scanner performs such transformation are, upon information and belief, described and implemented by non-public aspects of the Bluedrop Foot Scanner's software. Upon information and belief, discovery will yield additional information about how the Bluedrop Foot Scanner meets this claim limitation. Further, despite Podometrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

128. Claim 1 of the '723 patent requires “determining, by at least one of the processors, at any thermogram location, if at least one of the thermograms presents one of a plurality of patterns indicative of foot inflammation.” The Bluedrop Foot Scanner meets this limitation, including as shown above. The Bluedrop Foot Scanner receives temperature data from its “array of temperature sensors,” uses that data to create a thermogram, and compares six areas of each foot to determine a “hot spot.” A “hot spot” is indicative of foot inflammation. Further, despite Podometrics' request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

129. Claim 1 of the '723 patent requires “producing, by at least one of the processors, output information indicating a result of the determination of whether the thermograms present one of the plurality of patterns.” The Bluedrop Foot Scanner meets

this limitation, including as shown above. The device uses thermograms to determine the presence of “hot spots” which are indicative of foot inflammation. Further, despite Podimetrics’ request (in its August 8, 2022 letter), Bluedrop never provided any argument – other than the alleged lack of a “thermogram” because there is no “thermal foot display” – why the Bluedrop Foot Scanner does not meet this limitation.

130. By at least March 31, 2022, Bluedrop had actual knowledge of the ’723 patent. At least by that date, Bluedrop’s actions were – and continue to be – willful and intentional, including under the standard the Supreme Court articulated in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*

131. Upon information and belief, as of the date of Podimetrics’ March 31, 2022 letter Bluedrop had not yet sold, offered for sale, or imported the Bluedrop Foot Scanner in the United States. Notwithstanding Podimetrics’ March 31, 2022 letter, Bluedrop subsequently actively, knowingly, and intentionally began providing the Bluedrop Foot Scanner and instructions to its U.S. customers and users on how to set it up and to use it in an infringing manner. The Bluedrop Foot Scanner is not a staple article of commerce suitable for non-infringing uses.

132. By making, using, testing, offering for sale, selling, and/or importing the Bluedrop Foot Scanner, and by disseminating product descriptions and operating manuals, and by providing instructions to end-users on how to configure and use the Bluedrop Foot Scanner, Bluedrop has infringed and is infringing the ’723 patent, including at least Claim 1, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) – literally or under the doctrine of equivalents.

133. Podimetrics has been damaged by Bluedrop's infringement of the '723 patent and is suffering and will continue to suffer irreparable harm and damage as a result of this infringement unless such infringement is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, for the reasons set forth above, Podimetrics respectfully requests that this Court enter judgment in its favor, and against Bluedrop, and award relief including, but not limited to, the following:

- a) A judgment that Bluedrop has infringed one of more claims of the Patents-in-Suit;
- b) An order and judgment enjoining Bluedrop and its officers, agents, affiliates, employees, and attorneys, and all those persons acting or attempting to act in concert or participation with them, from further acts of infringement of the Patents-in-Suit;
- c) A judgment awarding Podimetrics all damages adequate to compensate it for Bluedrop's infringement of the Patents-in-Suit in accordance with 35 U.S.C. §§ 284, 285, 286, and 287, including all prejudgment and post-judgment interest at the maximum rate permitted by law;
- d) A judgment awarding Podimetrics enhanced damages as provided for in 35 U.S.C. § 284 or as otherwise permitted by law;
- e) A judgment awarding Podimetrics its costs and expenses pursuant to 35 U.S.C. § 284 or as otherwise permitted by law;
- f) A finding that this case is exceptional and awarding Podimetrics its

reasonable attorneys' fees as provided for in 35 U.S.C. § 285;

- g) An order directing Bluedrop to file with the Court and serve upon Podimetrics' counsel within thirty (30) days after entry of the order of injunction, a report setting forth the manner and form in which Bluedrop has complied with the injunction, including the provision relating to destruction and recall of infringing products and materials; and
- h) Such other and further relief to which Podimetrics may show itself to be entitled.

JURY DEMAND

Podimetrics demands trial by jury of all issues so triable in this action.

Dated: June 24, 2024

Respectfully submitted,

/s/ Amir H. Alavi

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