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(54) ULCER DETECTION APPARATUS AND METHOD WITH VARYING THRESHOLDS

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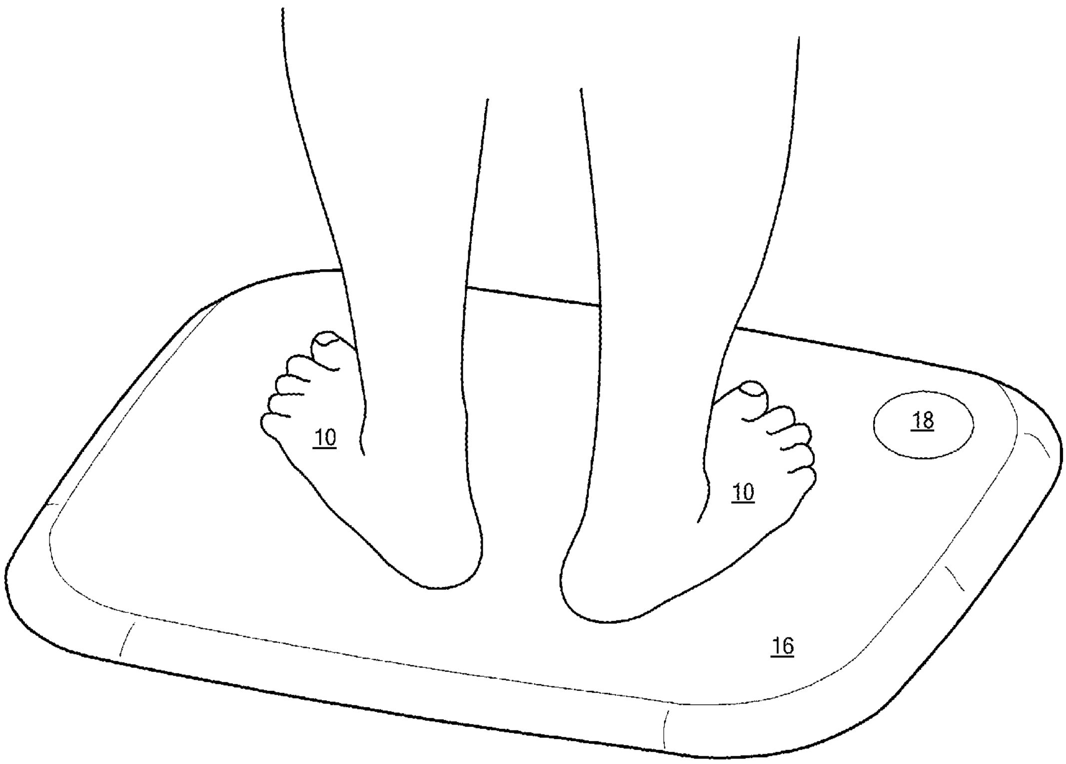
(57) **ABSTRACT**

A method determines the emergence of an ulcer or a pre-ulcer on at least one foot of a patient provides one or more processors and a modality for receiving at least one foot. The method generates, using a plurality of temperature sensors, discrete temperature data values after receipt of the at last one foot. The plurality of discrete temperature data values represents temperatures at different locations of the at least one foot. Next, the method compares, using a prescribed function, each of the discrete temperature data values to one of a plurality of different predetermined values. The predetermined values are different for at least two different locations of the at least one foot. The method then produces output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a result of comparing.



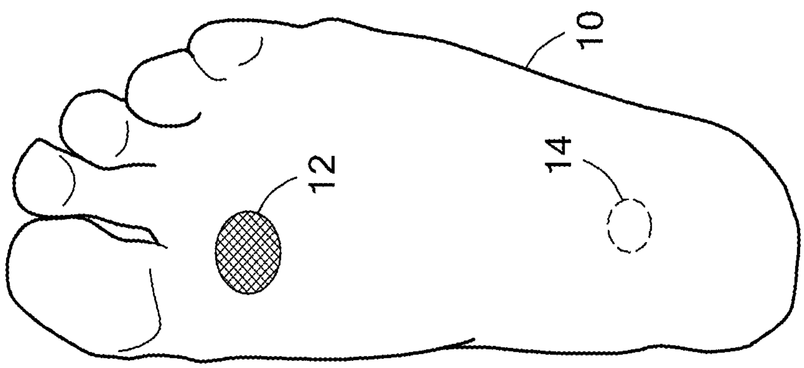


FIG. 1

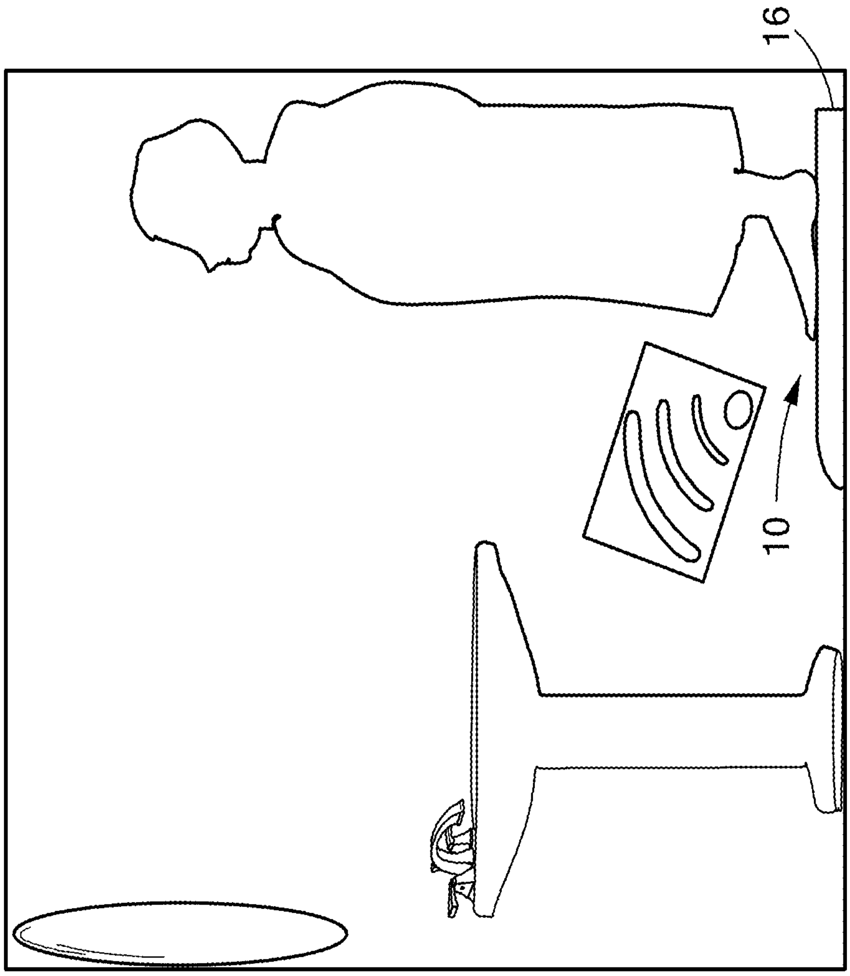


FIG. 2A

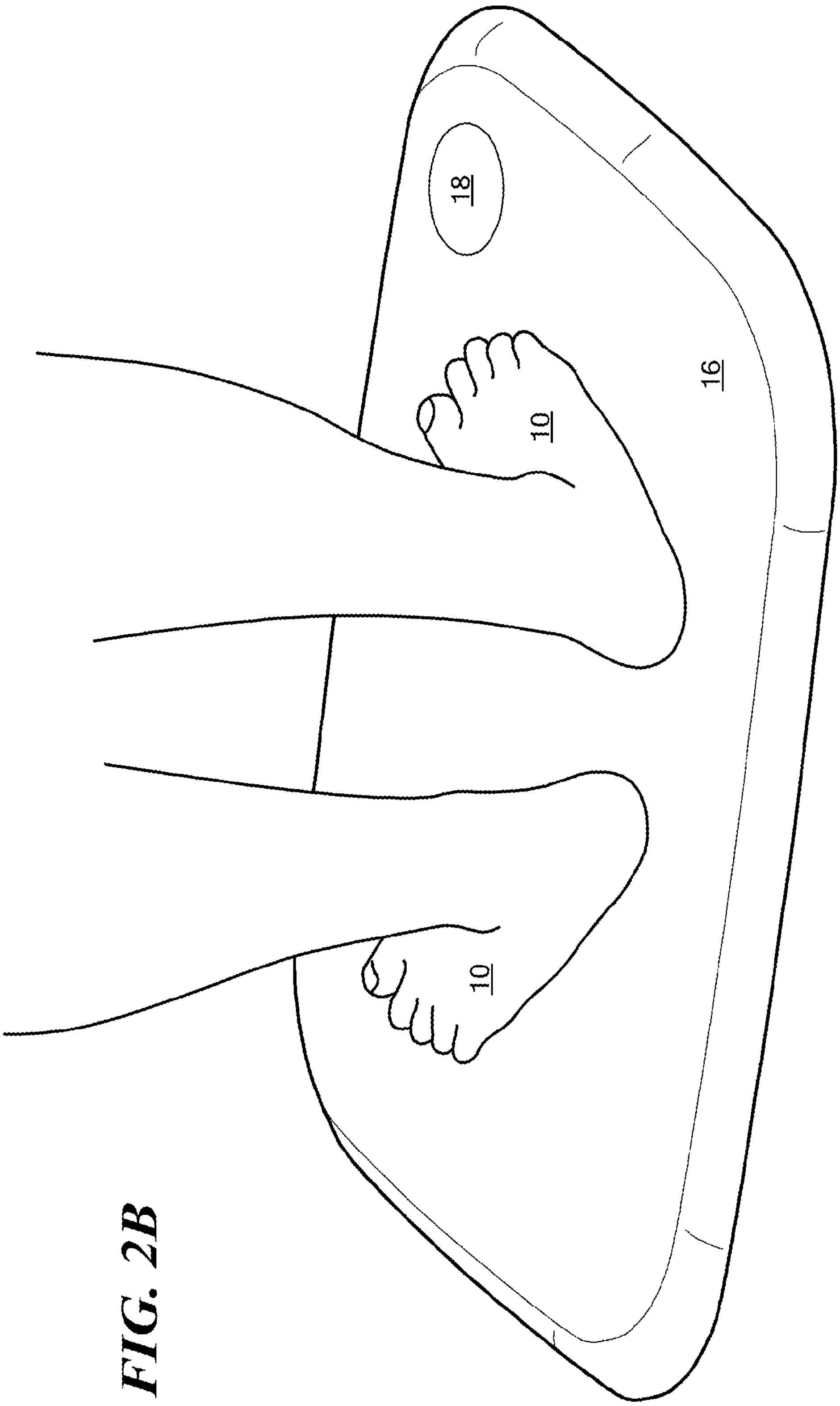


FIG. 2B

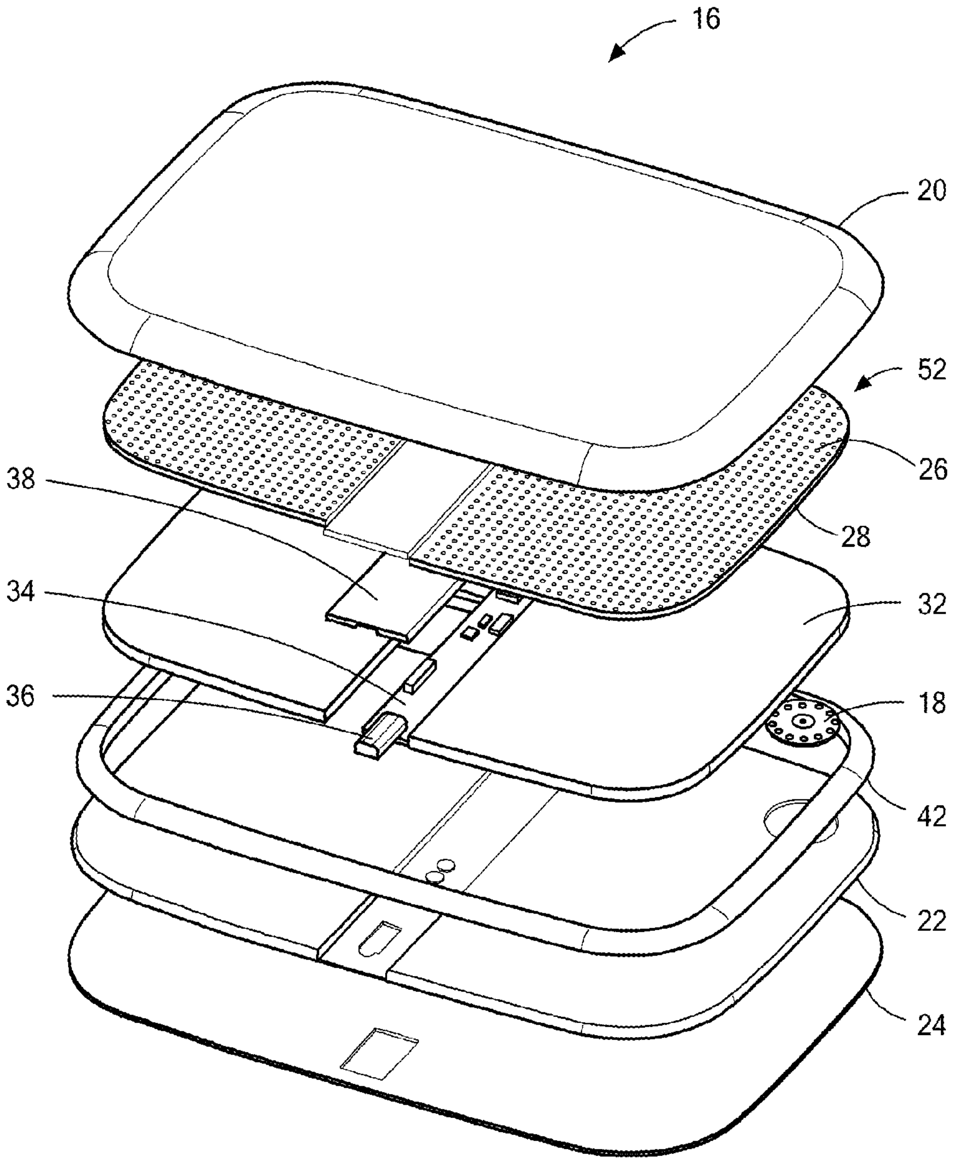


FIG. 3A

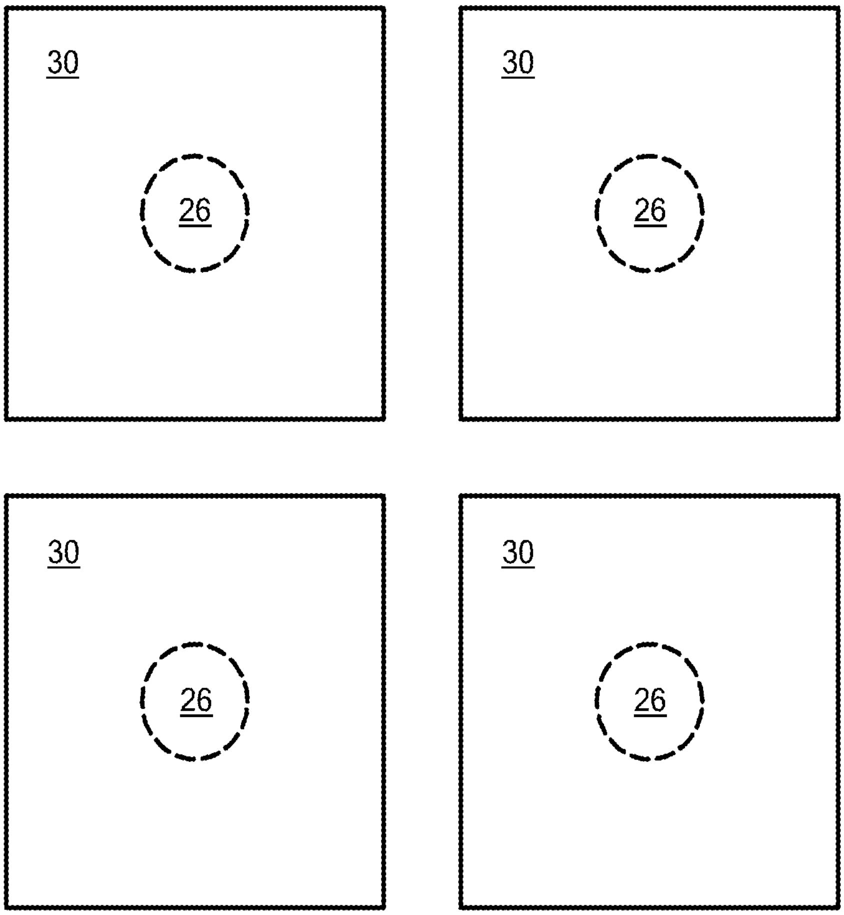


FIG. 3B

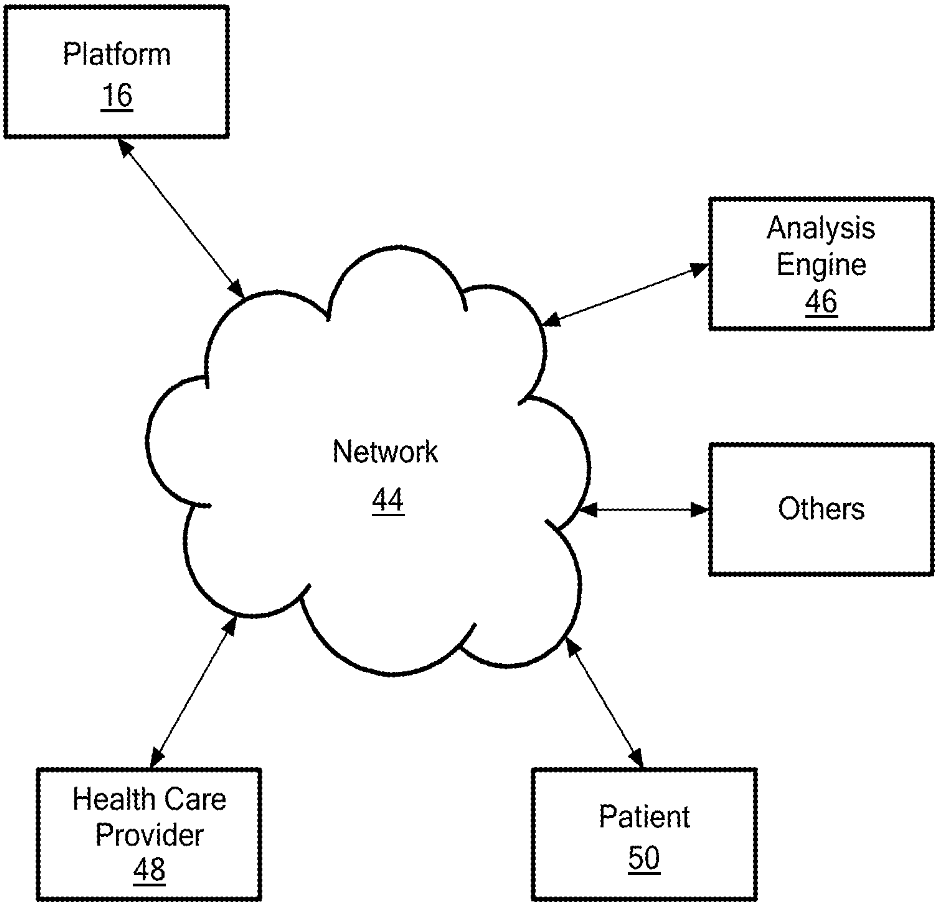

Platform
16
Analysis
Engine
46
Network
44
Others
Health Care
Provider
48
Patient
50

FIG. 4

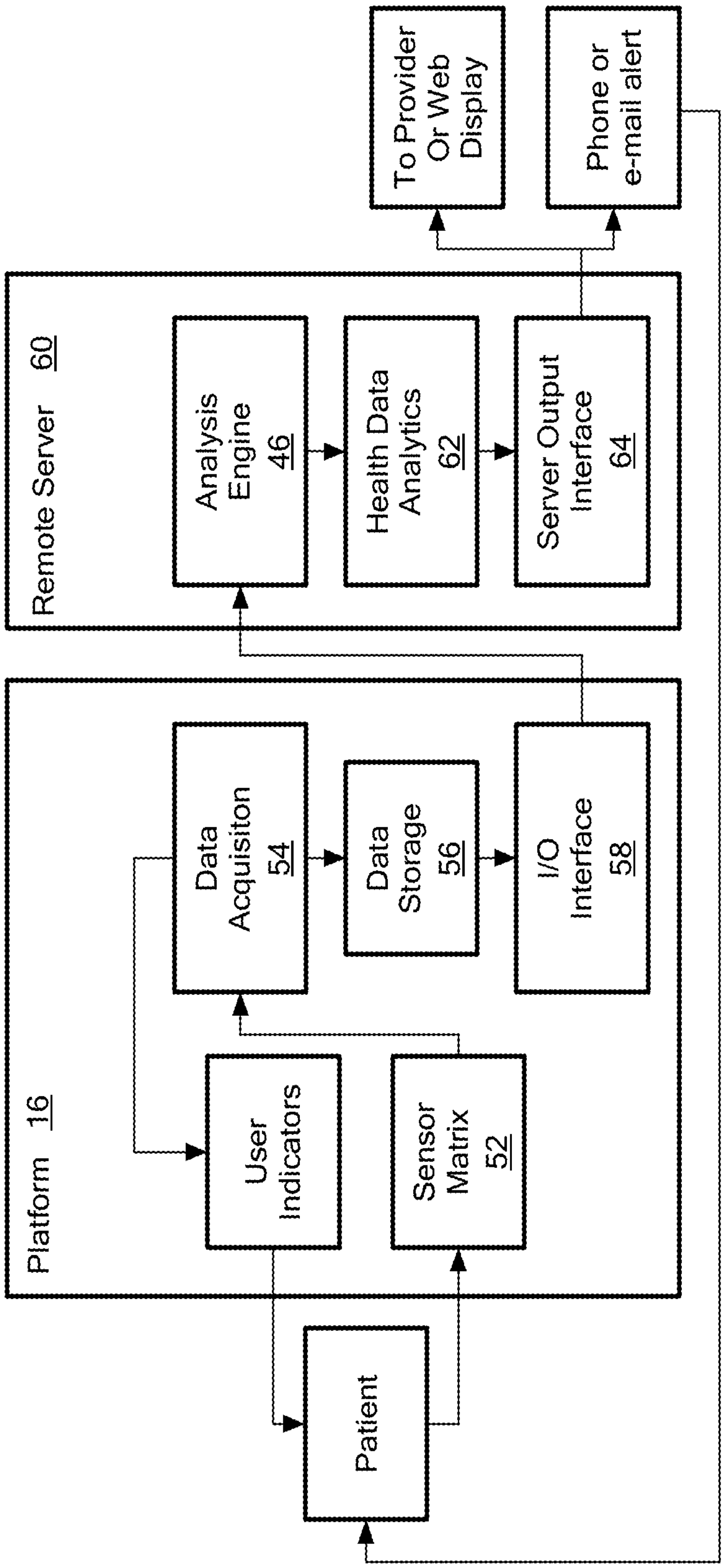

Patient
Platform 16
User Indicators
Sensor Matrix 52
Data Acquisiton 54
Data Storage 56
I/O Interface 58
Remote Server 60
Analysis Engine 46
Health Data Analytics 62
Server Output Interface 64
To Provider Or Web Display
Phone or e-mail alert

FIG. 5

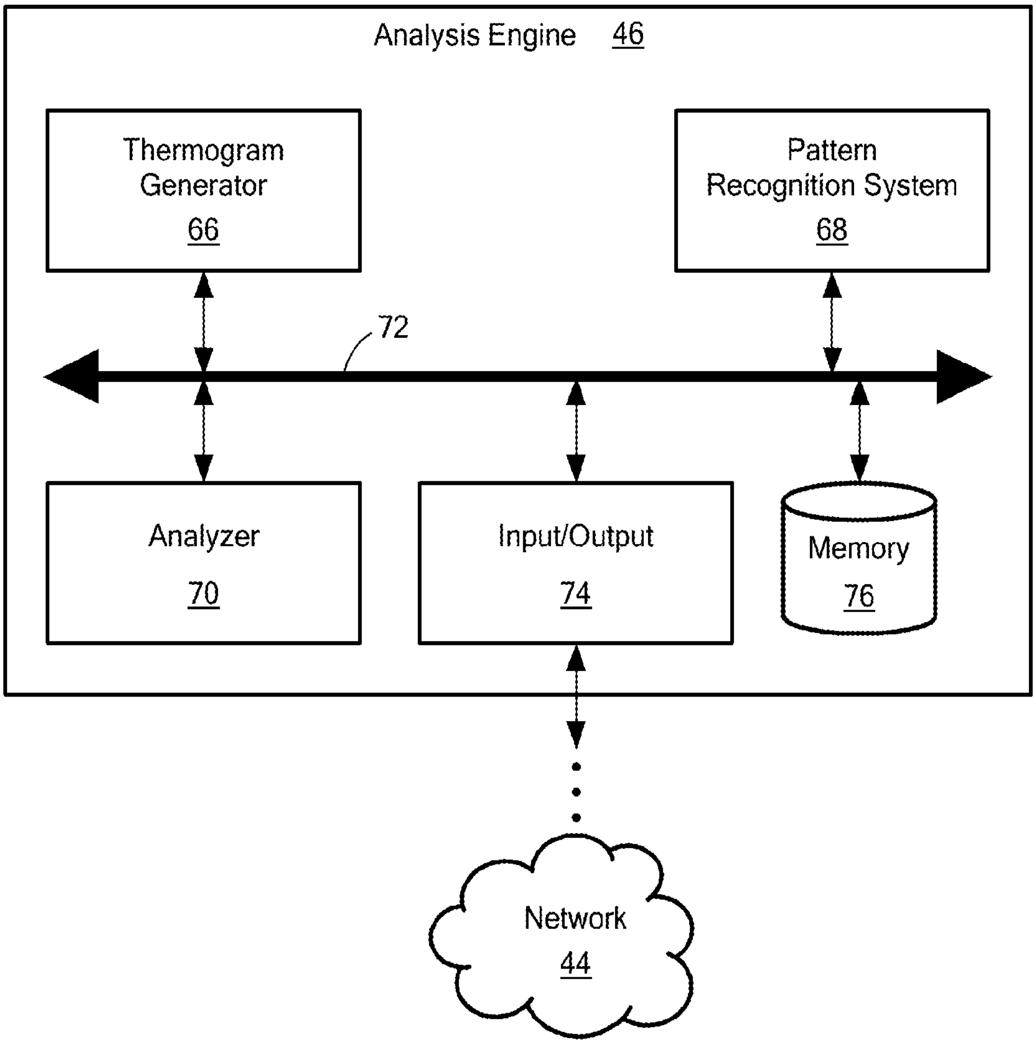

Analysis Engine 46
Thermogram Generator 66
Pattern Recognition System 68
72
Analyzer 70
Input/Output 74
Memory 76
Network 44

FIG. 6

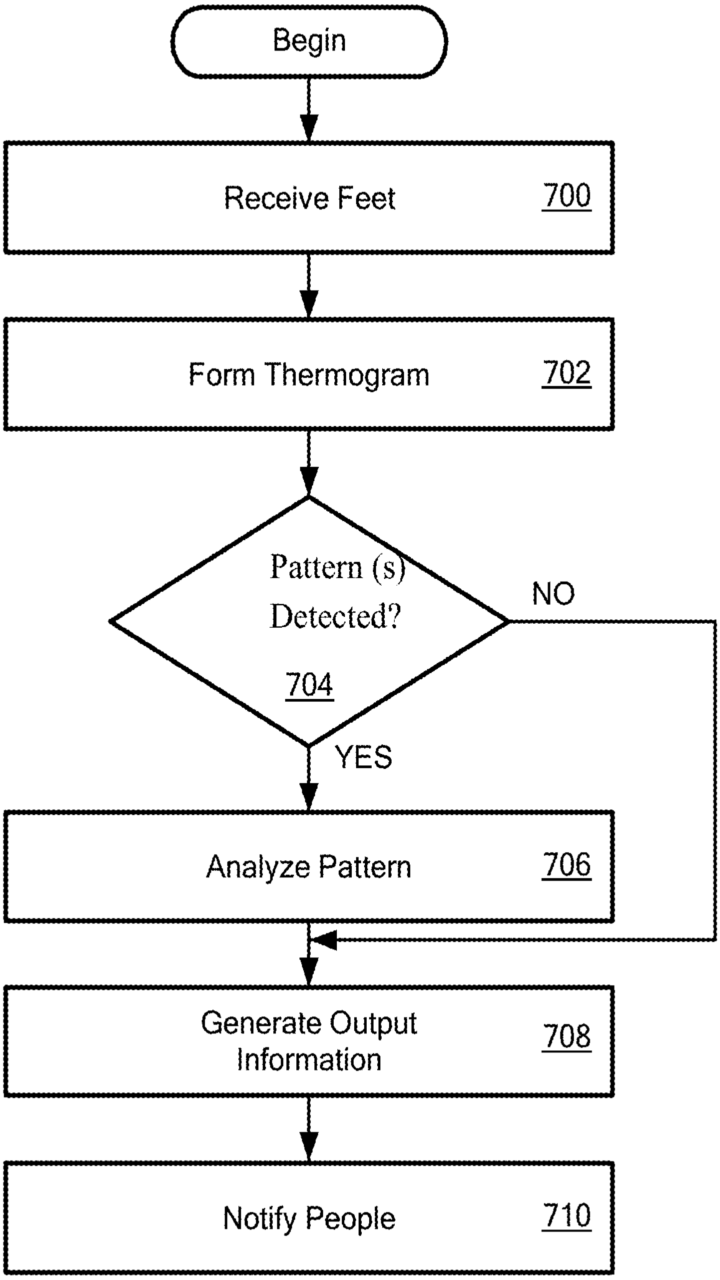

Begin
Receive Feet
700
Form Thermogram
702
Pattern (s) Detected?
704
NO
YES
Analyze Pattern
706
Generate Output Information
708
Notify People
710

FIG. 7

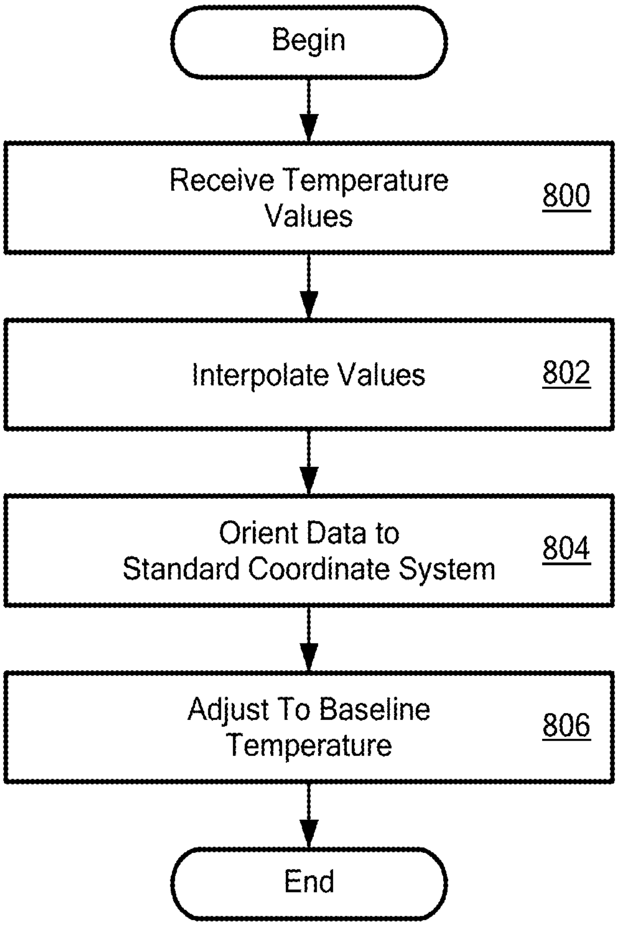

Begin
Receive Temperature Values
800
Interpolate Values
802
Orient Data to Standard Coordinate System
804
Adjust To Baseline Temperature
806
End

FIG. 8

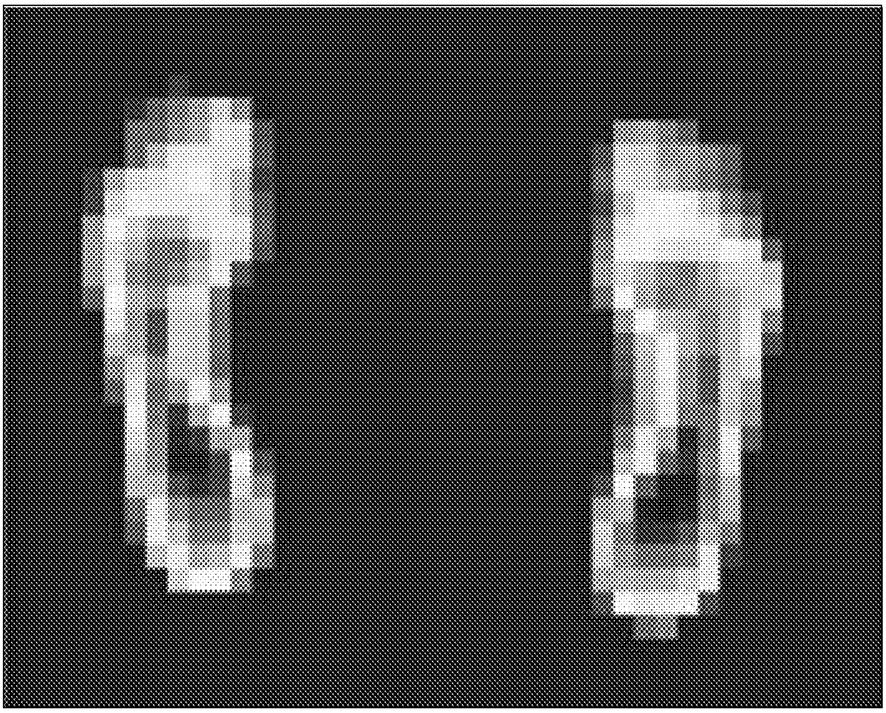


FIG. 9A

FIG. 9B

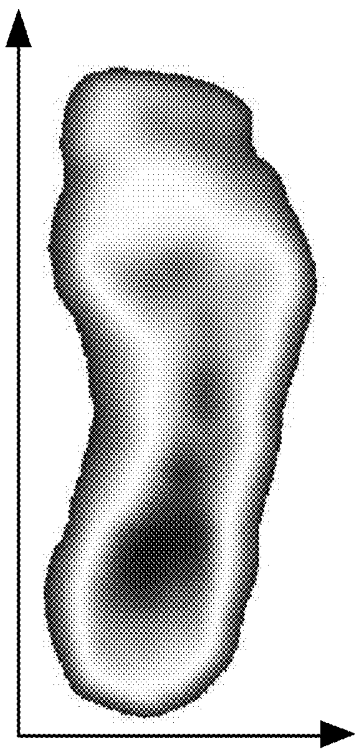


FIG. 9C

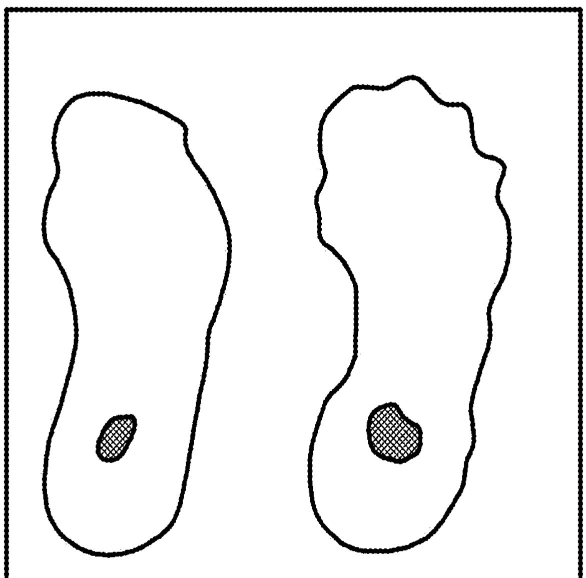


FIG. 9D

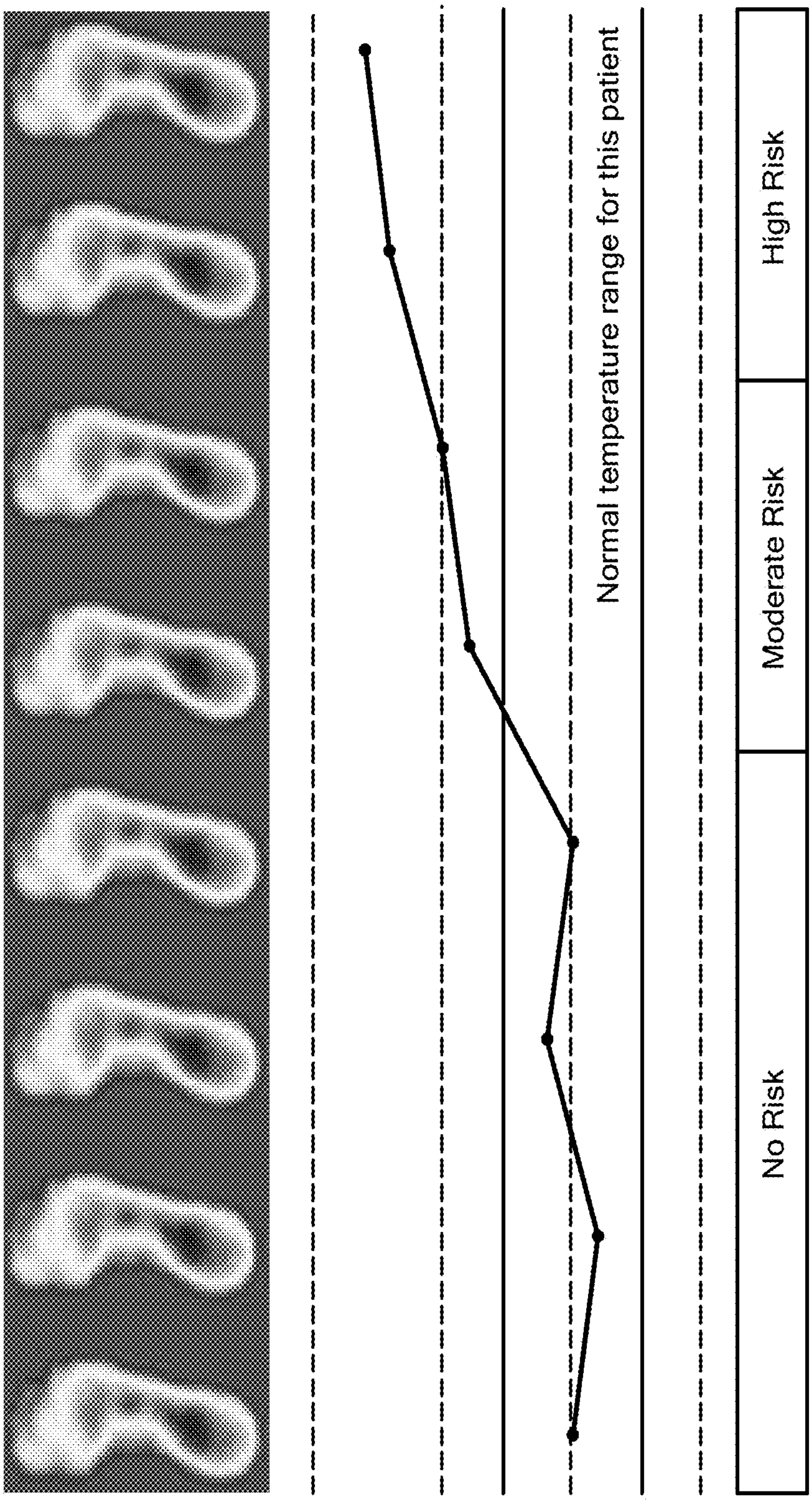

Normal temperature range for this patient
High Risk
Moderate Risk
No Risk

FIG. 10A

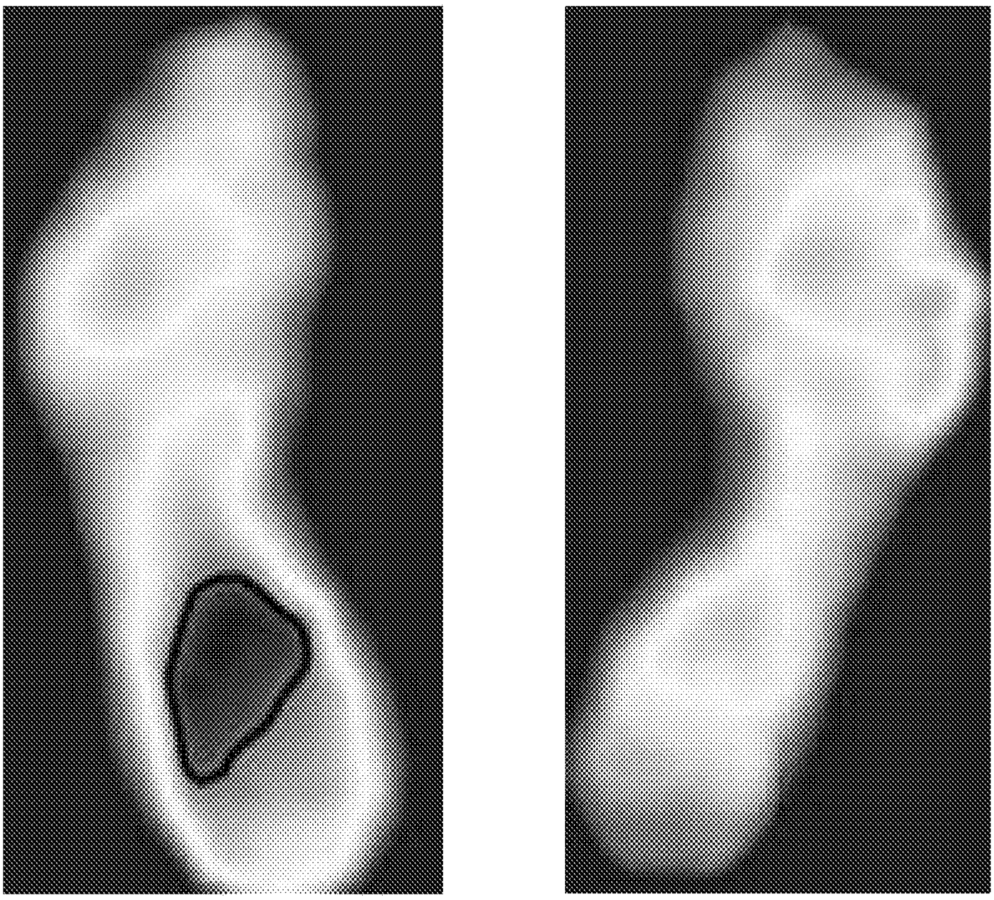
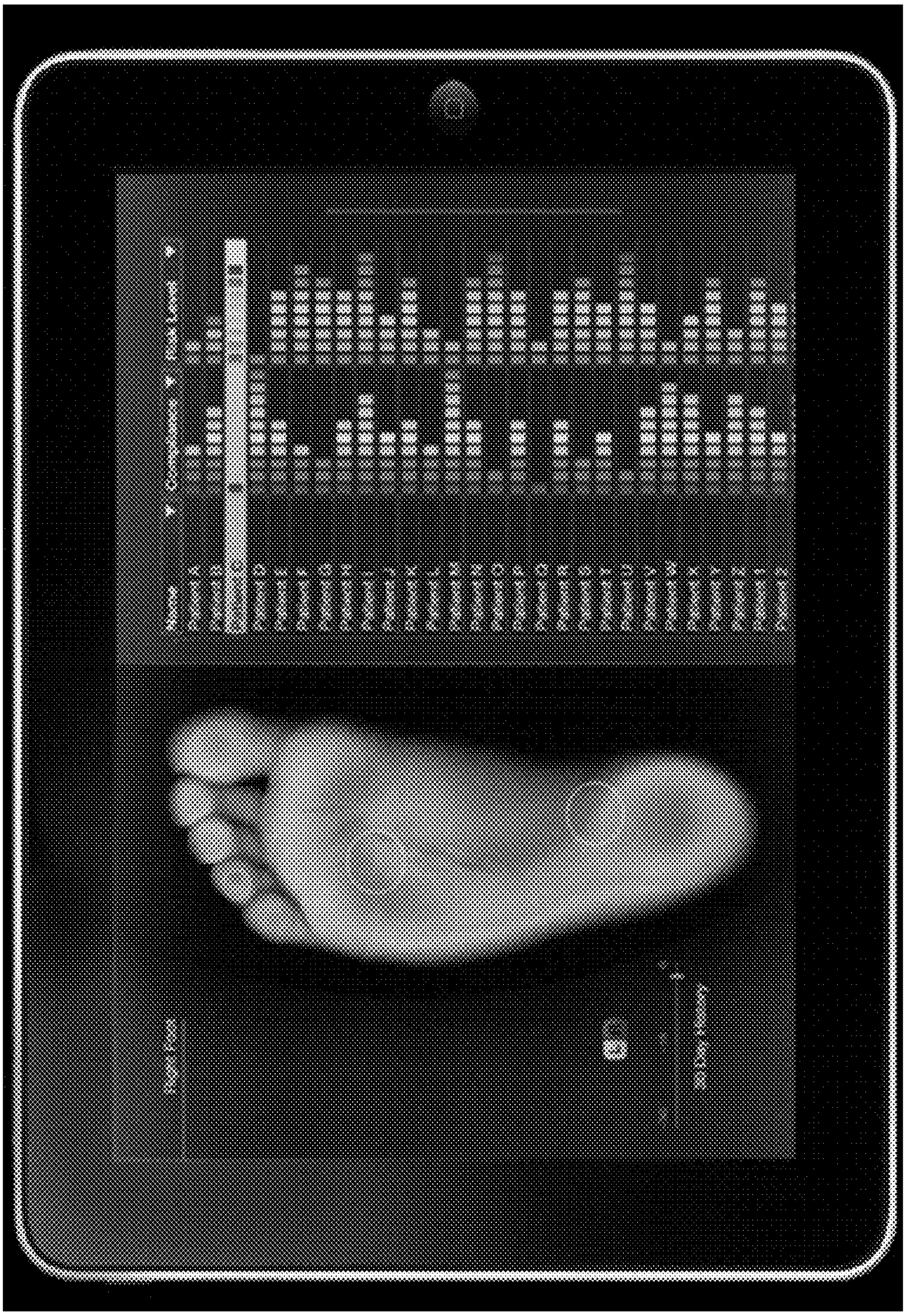
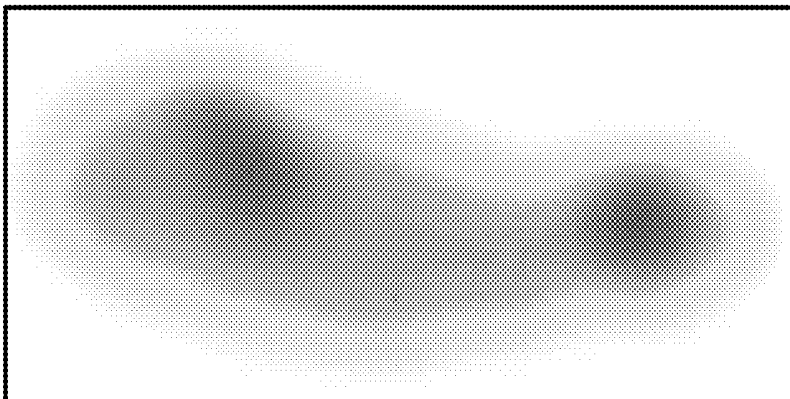


FIG. 10B

FIG. 11A





Patient	Last Checked	Risk Level
Patient A	1/2/12 12:00	20%
Patient B	1/6/12 2:10	35%
Patient C	1/5/12 3:00	80%
Patient D	1/5/12 6:30	40%
Patient E	1/5/12 5:00	25%
Patient F	1/3/12 11:00	35%
Patient G	1/4/12 7:30	30%
Patient H	1/5/12 5:00	40%

FIG.11B

ULCER DETECTION APPARATUS AND METHOD WITH VARYING THRESHOLDS

RELATED APPLICATIONS AND PATENTS

[0001] This patent application is related to the following patents and patent applications, the disclosures of which are incorporated herein, in their entireties, by reference:

[0002] 1. U.S. Pat. No. 9,259,178 (Attorney Docket Number 3891/1001),

[0003] 2. U.S. Pat. No. 9,095,305 (Attorney Docket Number 3891/1002),

[0004] 3. U.S. Pat. No. 9,271,672 (Attorney Docket Number 3891/1003),

[0005] 4. U.S. Pat. No. 9,326,723 (Attorney Docket Number 3891/1013),

[0006] 5. U.S. patent application Ser. No. 14/468,909, filed Aug. 26, 2014, entitled, "APPARATUS FOR MEASURING TEMPERATURE DISTRIBUTION ACROSS THE SOLE OF THE FOOT," assigned attorney docket number 3891/1012, and naming David Robert Linders and Brian Petersen as inventors.

[0007] 6. U.S. patent application Ser. No. 15/056,611, filed on Feb. 29, 2016, entitled, "METHOD AND APPARATUS FOR INDICATING THE EMERGENCE OF AN ULCER," assigned attorney docket number 3891/1016, and naming David Robert Linders, Jonathan David Bloom, Jeffrey Mark Engler, Brian Jude Petersen, Adam Geboff, and David Charles Kale and as inventors,

[0008] 7. U.S. patent application Ser. No. 15/144,658, filed on May 2, 2006, entitled, "METHOD AND APPARATUS FOR MONITORING FOOT IMFLAMMATION," assigned attorney docket number 3891/1017, and naming Brian Petersen, Jonathan David Bloom, David Robert Linders, and Jeffrey Mark Engler as inventors.

FIELD OF THE INVENTION

[0009] The invention generally relates to ulcers and, more particularly, the invention relates to devices for evaluating portions of living beings for ulcers.

BACKGROUND OF THE INVENTION

[0010] Open sores on an external surface of the body often form septic breeding grounds for infection, which can lead to serious health complications. For example, foot ulcers on the bottom of a diabetic's foot can lead to gangrene, leg amputation, or, in extreme cases, death. The healthcare establishment therefore recommends monitoring a diabetic's foot on a regular basis to avoid these and other dangerous consequences. Unfortunately, known techniques and products for monitoring foot ulcers, among other types of ulcers, often are inconvenient to use, unreliable, or inaccurate, thus reducing compliance by the very patient populations that need it the most.

SUMMARY OF VARIOUS EMBODIMENTS

[0011] In accordance with one embodiment of the invention, a method of determining the emergence of an ulcer or a pre-ulcer on at least one foot of a patient provides one or more processors and a modality for receiving at least one foot. To detect temperatures, the modality has a plurality of temperature sensors. The method generates, using the plurality of temperature sensors, a plurality of discrete temperature data values after receipt of the at last one foot. The plurality of discrete temperature data values represents temperatures at different locations of the at least one foot. Next, the method compares, using a prescribed function, at least one of the plurality of discrete temperature data values to one of a plurality of different predetermined values. The predetermined values preferably are different for at least two different locations of the at least one foot. The method then produces, using at least one of the processors, output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a function of said comparing.

[0012] Among other things, the prescribed function may subtract one of the discrete temperature data values from another temperature value of the at least one foot to produce a difference value. Thus, in that case, the method may compare the difference value with one of the different predetermined values. In illustrative embodiments, the method may produce output information indicating the emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is greater than the predetermined value. Conversely, the method may produce output information indicating no emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is not greater than the predetermined value. Moreover, the magnitude of the difference may indicate the relative risk of for the emergence of an ulcer or pre-ulcer on at least one foot. Those skilled in the art may select other functions. For example, the prescribed function may include an average or a weighted spatial or temporal average of the plurality of discrete temperature data values.

[0013] Various embodiments may compare by using discrete temperature data values at corresponding contralateral foot locations of a patient's two feet in the prescribed function. For example, the plurality of discrete temperature data values may include a first discrete temperature data value representing a first location on a patient's left foot, and a second temperature data value representing a second, contralateral location on the patient's right foot. The prescribed function may use both the first and second temperature data values to generate a function output value, and then compare the function output value against one of the plurality of predetermined values.

[0014] The method may compare ipsilateral foot locations too. For example, the plurality of discrete temperature data values may include an earlier temperature data value and a later temperature data value. Both the earlier and later temperature data values represent the same location of the same foot at different times. In that case, the method may compare the earlier and later discrete temperature data values in the prescribed function.

[0015] Some embodiments may use a thermogram. For example, the method may form, by at least one of the processors, at least one thermogram of the at least one foot from the discrete temperature data values. Each thermogram is formed as a spatially continuous data set of two-dimensional temperature values across the sole of one foot. Next, the method compares, using the prescribed function and the at least one thermogram, temperatures at first and second different locations on the at least one foot to respective different predetermined values of the plurality of different predetermined values.

[0016] In accordance with another embodiment of the invention, an apparatus for determining the emergence of an ulcer or a pre-ulcer on at least one foot of a patient includes one or more processors, and a modality for receiving at least one foot. The modality has a plurality of temperature sensors configured to generate a plurality of discrete temperature data values after receipt of the at last one foot. The plurality of discrete temperature data values represent temperatures at different locations of the at least one foot. The apparatus also has a comparator operatively coupled with the plurality of temperature sensors. The comparator is configured to compare, using a prescribed function, each of the plurality of discrete temperature data values to one of a plurality of different predetermined values. The predetermined values are different for at least two different discrete temperature data values that each represent different locations of the at least one foot. Moreover, the apparatus also has an analyzer operatively coupled with the comparator. The analyzer is configured to produce output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a function of the comparison of the comparator.

[0017] Illustrative embodiments of the invention are implemented as a computer program product having a computer usable medium with computer readable program code thereon. The computer readable code may be read and utilized by a computer system in accordance with conventional processes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Those skilled in the art should more fully appreciate advantages of various embodiments of the invention from the following "Description of Illustrative Embodiments," discussed with reference to the drawings summarized immediately below.

[0019] Those skilled in the art should more fully appreciate advantages of various embodiments of the invention from the following "Description of Illustrative Embodiments," discussed with reference to the drawings summarized immediately below.

[0020] FIG. **1** schematically shows a foot having a prominent foot ulcer and a pre-ulcer.

[0021] FIG. **2**A schematically shows one use and form factor that may be implemented in accordance with illustrative embodiments of the invention.

[0022] FIG. **2**B schematically shows an open platform that may be configured in accordance with illustrative embodiments of the invention.

[0023] FIG. **3**A schematically shows an exploded view of one type of open platform that may be configured in accordance with illustrative embodiments of the invention.

[0024] FIG. **3**B schematically shows a close up view of the platform with details of the pads and temperature sensors.

[0025] FIG. **4** schematically shows a network implementing of illustrative embodiments of the invention.

[0026] FIG. **5** schematically shows an overview of various components of illustrative embodiments of the invention.

[0027] FIG. **6** schematically shows details of a data processing module in accordance with illustrative embodiments of the invention.

[0028] FIG. **7** shows a process of monitoring the health of the patient's foot or feet in accordance with illustrative embodiments the invention.

[0029] FIG. **8** shows a process of forming a thermogram in accordance with illustrative embodiments of the invention.

[0030] FIGS. **9**A-**9**D schematically show the progression of the thermogram and how it is processed in accordance with one embodiment of the invention.

[0031] FIGS. **10**A and **10**B schematically show two different types of patterns that may be on the soles of a patient's foot indicating an ulcer or pre-ulcer.

[0032] FIGS. **11**A and **11**B schematically show two different user interfaces that may be displayed in accordance with illustrative embodiments of the invention.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0033] In illustrative embodiments, a method and apparatus analyze a patient's foot to determine the whether a new ulcer has emerged on its underside (i.e., on its sole). This permits patients, their healthcare providers, and/or their caregivers to intervene earlier, reducing the risk of more serious complications. To that end, a modality receives the patient's foot and generates temperature data that may be processed to form a thermogram. Illustrative embodiments also may not form a thermogram. Instead, the temperature data is unprocessed—i.e., they are just the discrete temperature values. If the thermogram or discrete temperature values present at least one of a number of prescribed patterns, then various embodiments produce output information indicating the emergence of an ulcer or pre-ulcer on the patient's foot.

[0034] Preferred embodiments do not necessarily use a uniform method of detecting the pattern. For example, such embodiments may compare a first pair of contralateral locations to one threshold temperature value, and another pair of contralateral locations to another, different threshold value. Details of illustrative embodiments are discussed below.

[0035] FIG. **1** schematically shows a bottom view of a patient's foot **10** that, undesirably, has an ulcer **12** and a pre-ulcer **14** (described below and shown in phantom since pre-ulcers **14** do not break through the skin). As one would expect, an ulcer **12** on this part of the foot **10** typically is referred to as a "foot ulcer **12**." Generally speaking, an ulcer is an open sore on a surface of the body generally caused by a breakdown in the skin or mucous membrane. Diabetics often develop foot ulcers **12** on the soles of their feet **10** as part of their disease. In this setting, foot ulcers **12** often begin as a localized inflammation that may progress to skin breakdown and infection.

[0036] It should be noted that discussion of diabetes and diabetics is but one example and used here simply for illustrative purposes only. Accordingly, various embodiments apply to other types of diseases (e.g., stroke, deconditioning, sepsis, friction, coma, etc. . . .) and other types of ulcers—such embodiments may apply generally where there is a compression or friction on the living being's body over an extended period of time. For example, various embodiments also apply to ulcers formed on different parts of the body, such as on the back (e.g., bedsores), inside of prosthetic sockets, or on the buttocks (e.g., a patient in a wheel chair). Moreover, illustrative embodiments apply to other types of living beings beyond human beings, such as other mammals (e.g., horses or dogs). Accordingly, discussion of diabetic human patients having foot ulcers **12** is for simplicity only and not intended to limit all embodiments of the invention.

[0037] Many prior art ulcer detection technologies known to the inventors suffered from one significant problem—patient compliance. If a diseased or susceptible patient does not regularly check his/her feet **10**, then that person may not learn of an ulcer **12** or a pre-ulcer **14** until it has emerged through the skin and/or requires significant medical treatment. Accordingly, illustrative embodiments implement an ulcer monitoring system in any of a variety of forms—preferably in an easy to use form factor that facilitates and encourages regular use.

[0038] FIGS. **2**A and **2**B schematically show one form factor, in which a patient/user steps on an open platform **16** that gathers data about that user's feet **10**. In this particular example, the open platform **16** is in the form of a floor mat placed in a location where he the patient regularly stands, such as in front of a bathroom sink, next to a bed, in front of a shower, on a footrest, or integrated into a mattress. As an open platform **16**, the patient simply may step on the top sensing surface of the platform **16** to initiate the process. Accordingly, this and other form factors favorably do not require that the patient affirmatively decide to interact with the platform **16**. Instead, many expected form factors are configured to be used in areas where the patient frequently stands during the course of their day without a foot covering. Alternatively, the open platform **16** may be moved to directly contact the feet **10** of a patient that cannot stand. For example, if the patient is bedridden, then the platform **16** may be brought into contact with the patient's feet **10** while in bed.

[0039] A bathroom mat or rug are but two of a wide variety of different potential form factors. Others may include a platform **16** resembling a scale, a stand, a footrest, a console, a tile built into the floor, or a more portable mechanism that receives at least one of the feet **10**. The implementation shown in FIGS. **2**A and **2**B has a top surface area that is larger than the surface area of one or both of the feet **10** of the patient. This enables a caregiver to obtain a complete view of the patient's entire sole, providing a more complete view of the foot **10**.

[0040] The open platform **16** also has some indicia or display **18** on its top surface they can have any of a number of functions. For example, the indicia can turn a different color or sound an alarm after the readings are complete, show the progression of the process, or display results of the process. Of course, the indicia or display **18** can be at any location other than on the top surface of the open platform **16**, such as on the side, or a separate component that communicates with the open platform **16**. In fact, in addition to, or instead of, using visual or audible indicia, the platform **16** may have other types of indicia, such as tactile indicia/feedback, our thermal indicia.

[0041] Rather than using an open platform **16**, alternative embodiments may be implemented as a closed platform **16**, such as a shoe or sock that can be regularly worn by a patient, or worn on an as-needed basis. For example, the insole of the patient's shoe or boot may have the functionality for detecting the emergence of a pre-ulcer **14** or ulcer **12**, and/or monitoring a pre-ulcer **14** or ulcer **12**.

[0042] To monitor the health of the patient's foot (discussed in greater detail below), the platform **16** of FIGS. **2**A and **2**B gathers temperature data about a plurality of different locations on the sole of the foot **10**. This temperature data provides the core information ultimately used to determine the health of the foot **10**. FIG. **3**A schematically shows an exploded view of the open platform **16** configured and arranged in accordance with one embodiment of the invention. Of course, this embodiment is but one of a number of potential implementation and, like other features, is discussed by example only.

[0043] As shown, the platform **16** is formed as a stack of functional layers sandwiched between a cover **20** and a rigid base **22**. For safety purposes, the base preferably has rubberized or has other non-skid features on its bottom side. FIG. **3**A shows one embodiment of this non-skid feature as a non-skid base **24**. The platform **16** preferably has relatively thin profile to avoid tripping the patient and making it easy to use.

[0044] To measure foot temperature, the platform **16** has an array or matrix of temperature sensors **26** fixed in place directly underneath the cover **20**. More specifically, the temperature sensors **26** are positioned on a relatively large printed circuit board **28**. The sensors **26** preferably are laid out in a two-dimensional array/matrix of stationary contact sensors on the printed circuit board **28**. Although FIG. **3**A shows the array as two sub-arrays, some embodiments form the array as a single array across the platform **16**. The pitch or distance between the preferably is relatively small, thus permitting more temperature sensors **26** on the array. Among other things, the temperature sensors **26** may include temperature sensitive resistors (e.g., printed or discrete components mounted onto the circuit board **28**), thermocouples, fiberoptic temperature sensors, or a thermochromic film. Accordingly, when used with temperature sensors **26** that require direct contact, illustrative embodiments form the cover **20** with a thin material having a relatively high thermal conductivity. The platform **16** also may use temperature sensors **26** that can still detect temperature through a patient's socks.

[0045] Other embodiments may use noncontact temperature sensors **26**, such as infrared detectors. Indeed, in that case, the cover **20** may have openings to provide a line of sight from the sensors **26** to the sole of the foot **10**. Accordingly, discussion of contact sensors is by example only and not intended to limit various embodiments. As discussed in greater detail below and noted above, regardless of their specific type, the plurality of sensors **26** generate a plurality of corresponding temperature data values for a plurality of portions/spots on the patient's foot **10** to monitor the health of the foot **10**.

[0046] Some embodiments also may use pressure sensors for various functions, such as to determine the orientation of the feet **10**, to measure the weight of the user, and/or to automatically begin the measurement process. Among other things, the pressure sensors may include piezoelectric, resistive, capacitive, or fiber-optic pressure sensors. This layer of the platform **16** also may have additional sensor modalities beyond temperature sensors **26** and pressure sensors, such as positioning sensors, GPS sensors, accelerometers, gyroscopes, and others known by those skilled in the art.

[0047] To reduce the time required to sense the temperature at specific points, illustrative embodiments position an array of heat conducting pads **30** over the array of temperature sensors **26**. To illustrate this, FIG. **3**B schematically shows a small portion of the array of temperature sensors **26** showing four temperature sensors **26** and their pads **30**. The temperature sensors **26** are drawn in phantom because they preferably are covered by the pads **30**. Some embodiments do not cover the sensors **26**, however, and simply thermally connect the sensors **26** with the pads **26**.

[0048] Accordingly, each temperature sensor **26** has an associated heat conducting pad **30** that channels heat from one two dimensional portion of the foot **10** (considered a two dimensional area although the foot may have some depth dimensionality) directly to its exposed surface. The array of conducting pads **30** preferably takes up the substantial majority of the total surface area of the printed circuit board **28**. The distance between the pads **30** thermally isolates them from one another, thus eliminating thermal short-circuits.

[0049] For example, each pad **30** may have a square shape with each side having a length of between about 0.1 and 1.0 inches. The pitch between pads **30** thus is less than that amount. Accordingly, as a further detailed example, some embodiments may space the temperature sensors **26** about 0.4 inches apart with 0.25 inch (per side) square pads **30** oriented so that each sensor **26** is at the center of the square pads **30**. This leaves an open region (i.e., a pitch) of about 0.15 inches between the square pads **30**. Among other things, the pads **30** may be formed from a film of thermally conductive metal, such as a copper.

[0050] As suggested above, some embodiments do not use an array of temperature sensors **26**. Instead, such embodiments may use a single temperature sensor **26** that can obtain a temperature reading of most or all of the sole. For example, a single sheet of a heat reactive material, such as a thermochromic film (noted above), or similar apparatus should suffice. As known by those in the art, a thermochromic film, based on liquid crystal technology, has internal liquid crystals that reorient to produce an apparent change in color in response to a temperature change, typically above the ambient temperature. Alternatively, one or more individual temperature sensors **26**, such as thermocouples or temperature sensor resistors, may be movable to take repeated temperature readings across the bottom of the foot **10**.

[0051] To operate efficiently, the open platform **16** should be configured so that its top surface contacts substantially the entire sole of the patient's foot **10**. To that end, the platform **16** has a flexible and movable layer of foam **32** or other material that conforms to the user's foot **10**. For example, this layer should conform to the arch of the foot **10**. Of course, the sensors **26**, printed circuit board **28**, and cover **20** also should be similarly flexible and yet robust to conform to the foot **10** in a corresponding manner. Accordingly, the printed circuit board **28** preferably is formed largely from a flexible material that supports the circuit. For example, the printed circuit board **28** may be formed primarily from a flex circuit that supports the temperature sensors **26**, or it may be formed from strips of material that individually flex when receiving feet. Alternative embodiments may not have such flexibility (e.g., formed from conventional printed circuit board material, such as FR-4) and thus, produce less effective data.

[0052] The rigid base **22** positioned between the foam **32** and the non-skid base **24** provides rigidity to the overall structure. In addition, the rigid base **22** is contoured to receive a motherboard **34**, a battery pack **36**, a circuit housing **38**, and additional circuit components that provide further functionality. For example, the motherboard **34** may contain integrated circuits and microprocessors that control the functionality of the platform **16**.

[0053] In addition, the motherboard **34** also may have a user interface/indicia display **18** as discussed above, and a communication interface **40** (FIG. **5**) to connect to a larger network **44**, such as the Internet. The communication interface **40** may connect wirelessly or through a wired connection with the larger network **44**, implementing any of a variety of different data communication protocols, such as Ethernet. Alternatively, the communication interface **40** can communicate through an embedded Bluetooth or other short range wireless radio that communicates with a cellular telephone network **44** (e.g., a 3G or 4G network).

[0054] The platform **16** also may have edging **42** and other surface features that improve its aesthetic appearance and feel to the patient. The layers may be secured together using one or more of an adhesive, snaps, nuts, bolts, or other fastening devices.

[0055] Although it gathers temperature and other data about the patient's foot, illustrative embodiments may locate additional logic for monitoring foot health at another location. For example, such additional logic may be on a remote computing device. To that and other ends, FIG. **4** schematically shows one way in which the platform **16** can communicate with a larger data network **44** in accordance with various embodiments the invention. As shown, the platform **16** may connect with the Internet through a local router, through its local area network, or directly without an intervening device. This larger data network **44** (e.g., the Internet) can include any of a number of different endpoints that also are interconnected. For example, the platform **16** may communicate with an analysis engine **46** that analyzes the thermal data from the platform **16** and determines the health of the patient's foot **10**. The platform **16** also may communicate directly with a healthcare provider **48**, such as a doctor, nurse, relative, and/or organization charged with managing the patient's care. In fact, the platform **16** also can communicate with the patient, such as through text message, telephone call, e-mail communication, or other modalities as the system permits.

[0056] FIG. **5** schematically shows a block diagram of a foot monitoring system, showing the platform **16** and the network **44** with its interconnected components in more detail. As shown, the patient communicates with the platform **16** by standing on or being received in some manner by the array of sensors **26**, which is represented in this figure as a "sensor matrix **52**." A data acquisition block **54**, implemented by, for example, the motherboard **34** and circuitry shown in FIG. **6**, controls acquisition of the temperature and other data for storage in a data storage device **56**. Among other things, the data storage device **56** can be a volatile or nonvolatile storage medium, such as a hard drive, high-speed random-access-memory ("RAM"), or solid-state memory. The input/output interface port **40**, also controlled by the motherboard **34** and other electronics on the platform **16**, selectively transmits or forwards the acquired data from the storage device to the analysis engine **46** on a remote computing device, such as a server **60**. The data acquisition block **54** also may control the user indicators/displays **18**, which provide feedback to the user through the above mentioned indicia (e.g., audible, visual, or tactile).

[0057] As noted above and discussed in greater detail below with regard to FIGS. **7** and **8**, the analysis engine **46**, on the remote server **60**, analyzes the data received from the platform **16** in conjunction with a health data analytics module **62**. A server output interface **64** forwards the processed output information/data from the analysis engine **46** and health data analytics module **62** as an output message toward others across the network **44**, such as to a provider, a web display, or to the user via a phone, e-mail alert, text alert, or other similar way.

[0058] This output message may have the output information in its relatively raw form for further processing. Alternatively, this output message may have the output information formatted in a high-level manner for easy review by automated logic or a person viewing the data. Among other things, the output message may indicate the actual emergence of an ulcer **12** or a pre-ulcer **14**, the risk of the emergence of an ulcer **12** or a pre-ulcer **14**, or simply that the foot **10** is healthy and has no risks of ulcer **12** or pre-ulcer **14**. In addition, this output message also may have information that helps an end-user or healthcare provider **48** monitor an ulcer **12** or pre-ulcer **14**.

[0059] Using a distributed processing arrangement like that shown in FIG. **5** has a number of benefits. Among other things, it permits the platform **16** to have relatively simple and inexpensive components that are unobtrusive to the patient. Moreover, this permits a "software-as-a-service" business model ("SAAS model"), which, among other things, permits more flexibility in the functionality, typically easier patient monitoring, and more rapid functional updates. In addition, the SAAS model facilitates accumulation of patient data to improve analytic capability.

[0060] Some embodiments may distribute and physically position the functional components in a different manner. For example, the platform **16** may have the analysis engine **46** on its local motherboard **34**. In fact, some embodiments provide the functionality entirely on the platform **16** and/or within other components in the local vicinity of the platform **16**. For example, all of those functional elements (e.g., the analysis engine **46** and other functional elements) may be within the housing formed by the cover **20** and the rigid base **22**. Accordingly, discussion of a distributed platform **16** is but one of a number of embodiments that can be adapted for a specific application or use.

[0061] Those skilled in the art can perform the functions of the analysis engine **46** using any of a number of different hardware, software, firmware, and/or other non-known technologies. FIG. **6** shows several functional blocks that, with other functional blocks, may be configured to perform the functions of the analysis engine **46**. This figure simply shows the blocks and is illustrative of one way of implementing various embodiments, while FIGS. **7** and **8** describe some of their functions in greater detail.

[0062] Each of these components is operatively connected by any conventional interconnect mechanism. FIG. **6** simply shows a bus **72** communicating each the components. Those skilled in the art should understand that this generalized representation can be modified to include other conventional direct or indirect connections. Accordingly, discussion of the bus **72** is not intended to limit various embodiments.

[0063] Indeed, it should be noted that FIG. **6** only schematically shows each of these components. Those skilled in the art should understand that each of these components can be implemented in a variety of conventional manners, such as by using hardware, software, or a combination of hardware and software, across one or more other functional components. For example, the analyzer **70** may be implemented using a plurality of microprocessors executing firmware. As another example, the analyzer **70** may be implemented using one or more application specific integrated circuits (i.e., "ASICs") and related software, or a combination of ASICs, discrete electronic components (e.g., transistors), and microprocessors. Accordingly, the representation of the analyzer **70** and other components in a single box of FIG. **6** is for simplicity purposes only. In fact, in some embodiments, the analyzer **70** of FIG. **6** is distributed across a plurality of different machines—not necessarily within the same device.

[0064] It should be reiterated that the representation of FIG. **6** is a significantly simplified representation of an actual analysis engine Those skilled in the art should understand that such a device has many other physical and functional components, such as central processing units, packet processing modules, and short-term memory. Accordingly, this discussion is in no way intended to suggest that FIG. **6** represents all of the elements of the analysis engine.

[0065] In summary, the analysis engine **46** of FIG. **6** has an optional thermogram generator **66** configured to form a thermogram of the patient's foot **10** or feet **10** based on a plurality of temperature readings from the bottom of the foot **10**, and a pattern recognition system **68** configured to determine whether the thermogram or the plurality of temperature readings from the temperature sensors presents any of a number of different prescribed patterns. The pattern recognition system **68** may have a comparator (not shown) to make various comparisons. Pattern data and other information may be stored in a local memory **76**. As discussed below, if the thermogram presents any of these prescribed patterns, then the foot **10** may be unhealthy in some manner (e.g., having a pre-ulcer **14** or an ulcer **12**).

[0066] The analysis engine **46** also has an analyzer **70** configured to produce the above noted output information, which indicates any of a number of different conditions of the foot **10**. For example, the output information may indicate the risk that an ulcer **12** will emerge, the emergence of a pre-ulcer **14** (i.e., the first indication of a pre-ulcer **14**), the progression of a known ulcer **12**, or the emergence of a new ulcer **12** (i.e., the first indication of any given ulcer **12** to the patient and associated support). Communicating through some interconnect mechanism, such as a bus **72** or network connection, these modules cooperate to determine the status of the foot **10**, which may be transmitted or forwarded through an input/output port **74** that communicates with the prior noted parties across the larger data network **44**.

[0067] FIG. **7** shows a process that uses the various components described above in FIGS. **1** through **6** to determine the health of the patient's foot **10**. It should be noted that this process is a simplified, high level summary of a much larger process and thus, should not be construed to suggest that only these steps are required. In addition, some of the steps may be performed in a different order than those described below. Although functions and processes of this process are described as being executed by the functional blocks in FIGS. **5** and **6**, some embodiments can be executed by other functional components.

[0068] The process begins at step **700**, in which the platform **16** receives the patient's feet **10** on its top surface, which may be considered a foot receiving area. For example, as shown in FIG. **2**A, the patient may step on the open platform **16** in front of the bathroom sink while washing her hands, brushing her teeth, or performing some other routine, frequent daily task. Presumably, the platform **16** is energized before the patient steps onto it. Some embodiments, however, may require that the platform **16** be affirmatively energized by the patient turning on power in some manner (e.g., actuating a power switch). Other embodiments, however, normally may operate in a low power, conservation mode (a "sleep mode") that rapidly turns on in response to a stimulus, such as receipt of the patient's feet **10**.

[0069] Accordingly, the platform **16** controls the sensor array to measure the temperature at the prescribed portions of the patient's foot/sole. For example, the platform **16** may measure the temperature at six prescribed points on each of the patient's two feet/soles. As another example, the platform **16** may measure the temperature at many other points on the patient's feet. At the same time, the user indicator display **18** may deliver affirmative feedback to the patient by any of the above discussed ways. After the patient steps on the platform **16**, the temperature sensors **26** may take a relatively long time to ultimately make their readings. For example, this process can take between **30** to **60** seconds. Many people, however, do not have that kind of patience and thus, may step off the platform **16** before it has completed its analysis. This undesirably can lead to inaccurate readings. In addition, these seemingly long delay times can reduce compliance.

[0070] The inventors recognized these problems. Accordingly, illustrative embodiments of the invention do not require such long data acquisition periods. Instead, the system can use conventional techniques to extrapolate a smaller amount of real temperature data (e.g., a sparer set of the temperature data) to arrive at an approximation of the final temperature at each point of the foot. For example, this embodiment may use techniques similar to those used in high speed thermometers to extrapolate the final temperature data using only one to three seconds of actual temperature data.

[0071] This step therefore produces a matrix of discrete temperature values across the foot **10** or feet **10**. FIG. **9**A graphically shows one example of this discrete temperature data for two feet **10**. As discrete temperature values, this representation does not have temperature information for the regions of the foot **10** between the temperature sensors **26**. In some embodiments, using this discrete temperature data as shown in FIG. **9**A, the process optionally forms a thermogram of the foot **10** or feet **10** under examination (step **702**). Other embodiments, however, do not form a thermogram. Steps taken by various embodiments that implement at thermogram may apply equally to various embodiments that do not implement a thermogram. Instead, in those latter embodiments, the various steps that require a thermogram are performed on selected discrete temperature values.

[0072] 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 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**.

[0073] Momentarily turning away from FIG. **7**, FIG. **8** shows a process that step **702** uses to form a thermogram in the embodiments that do form a thermogram. This discussion will return to FIG. **7** and proceed from step **702** after completing the thermogram formation process of FIG. **8**. It should be noted that, in a manner similar to FIG. **7**, the process of FIG. **8** is a simplified, high level summary of a larger process and thus, should not be construed to suggest that only these steps are required. In addition, some of the steps may be performed in a different order than those described below. In a manner similar to the functions and processes of FIG. **7**, the functions and processes described with regard to this process also can be executed by the functional blocks in FIGS. **5** and **6**, or by other functional components.

[0074] The process of forming a thermogram begins at step **800**, in which the thermogram generator **66** of the analysis engine **46** receives the plurality of temperature values, which, as noted above, are graphically shown by FIG. **9**A. Of course, the thermogram generator **66** typically receives those temperature values as raw data. The depiction in FIG. **9**A therefore is simply for illustration purposes only.

[0075] After receiving the temperature values, the process begins calculating the temperatures between the temperature sensors **26**. To that end, the process uses conventional interpolation techniques to interpolate the temperature values in a manner that produces a thermogram as noted above (step **802**). Accordingly, for a thermogram of a planar thermodynamic system at steady state, the process may be considered to increase the spatial resolution of the data.

[0076] Among other ways, some embodiments may use Laplace interpolation between the temperatures observed at each temperature sensor **26**. Laplace interpolation is appropriate for this function given its physical relevance—the heat equation should simplify to the Laplace equation under the assumption of steady state. The interpolant may be constructed by applying a second-order discrete finite difference Laplacian operator to the data, imposing equality conditions on the known temperatures at the sensors **26**, and solving the resulting sparse linear system using an iterative solver, such as GMRES.

[0077] FIG. **9**B schematically shows one example of the thermogram at this stage of the process. This figure should be contrasted with FIG. **9**A, which shows a more discrete illustration of the soles of the feet **10**.

[0078] At this point, the process is considered to have formed the thermogram. For effective use, however, it nevertheless still may require further processing. Step **804** therefore orients the data/thermogram to a standard coordinate system. To that end, the process may determine the location of the sole of each foot **10**, and then transform it into a standard coordinate system for comparison against other temperature measurements on the same foot **10**, and on the other foot **10**. This ensures that each portion of the foot **10** may be compared to itself from an earlier thermogram. FIG. **9**C schematically shows one example of how this step may reorient the thermogram of FIG. **9**B.

[0079] The position and orientation of the foot **10** on the platform **16** therefore is important when performing this step. For example, to determine the position and orientation of the foot **10**, the analysis engine **46** and its thermogram generator **66** simply may contrast the regions of elevated temperature on the platform **16** (i.e., due to foot contact) with those at ambient temperature. Other embodiments may use pressure sensors to form a pressure map of the foot **10**.

[0080] The process may end at this point, or continue to step **806**, to better contrast warmer portions of the foot **10** against other portions of the foot **10**. FIG. **9**D schematically shows a thermogram produced in this manner from the thermogram of FIG. **9**C. This figure more clearly shows two hotspots on the foot **10** than FIG. **9**C. To that end, the process determines the baseline or normal temperature of the foot **10** for each location within some tolerance range. The amount to which the actual temperature of a portion of the foot **10** deviates from the baseline temperature of that portion of the foot **10** therefore is used to more readily show hotspots.

[0081] For example, if the deviation is negative, the thermogram may have some shade of blue, with a visual scale of faint blues being smaller deviations and richer blues being larger deviations. In a similar manner, positive deviations may be represented by some shade of red, with a visual scale of faint red being smaller deviations and richer reds being larger deviations. Accordingly, in this example, bright red portions of the thermogram readily show hotspots that may require immediate attention. Of course, other embodiments may use other colors or techniques for showing hotspots. Accordingly, discussion of color coding or specific colors is not intended to limit all embodiments.

[0082] Now that the thermogram generator **66** has generated the thermogram, with brighter hotspots and in an appropriate orientation, this discussion returns to FIG. **7** to determine if the thermogram presents or shows any of a number of prescribed patterns (step **704**) and then analyzes any detected pattern (step **706**) to determine if there are hotspots. In particular, as noted, an elevated temperature at a particular portion of the foot **10** may be indicative or predictive of the emergence and risk of a pre-ulcer **14** or ulcer **12** in the foot **10**. For example, temperature deviations of about 2 degrees C. or about 4 degrees F. in certain contexts can suggest emergence of an ulcer **12** or pre-ulcer **14**. Temperature deviations other than about two degrees C. also may be indicative of a pre-ulcer **14** or ulcer **12** and thus, 2 degrees C. and 4 degrees F. are discussed by example only. Accordingly, various embodiments analyze the thermogram to determine if the geography of the foot **10** presents or contains one or more of a set of prescribed patterns indicative of a pre-ulcer **14** or ulcer **12**. Such embodiments may analyze the visual representation of the thermogram, or just the data otherwise used to generate and display a thermogram image—without displaying the thermogram.

[0083] A prescribed pattern may include a temperature differential over some geography or portion of the foot **10** or feet **10**. The pattern may be analyzed by the either or both the thermogram generator **66** or the analyzer **70**. To that end, various embodiments contemplate different patterns that compare at least a portion of the foot **10** against other foot data. Among other things, those comparisons may include the following:

[0084] 1. A comparison of the temperature of the same portion/spot of the same foot **10** at different times (i.e., a temporal comparison of the same spot),

[0085] 2. A comparison of the temperatures of corresponding portions/spots of the patient's two feet **10** at the same time or at different times, and/or

[0086] 3. A comparison of the temperature of different portions/spots of the same foot **10** at the same time or at different times.

[0087] As an example of the first comparison, the pattern may show a certain region of a foot **10** has a temperature that is **4** F higher than the temperature at that same region several days earlier. FIG. **10**A schematically shows one example of this, in which a portion of the same foot **10** - - - the patient's left foot **10**, has a spot with an increased risk of ulceration.

[0088] As an example of the second comparison, the pattern may show that the corresponding portions of the patient's feet **10** have a temperature differential that is 4 degrees F. FIG. **10**B schematically shows an example of this, where the region of the foot **10** on the left (the right foot **10**) having a black border is hotter than the corresponding region on the foot **10** on the right (the left foot **10**).

[0089] As an example of the third comparison, the pattern may show localized hotspots and peaks within an otherwise normal foot **10**. These peaks may be an indication of pre-ulcer **14** or ulcer **12** emergence, or increased risk of the same, which, like the other examples, alerts caregiver and patient to the need for more vigilance.

[0090] Of course, various embodiments may make similar comparisons while analyzing the thermogram for additional patterns. For example, similar to the third comparison, the pattern recognition system **68** may have a running average of the temperature of the geography of the entire foot **10** over time. For any particular spot on the foot **10**, this running average may have a range between a high temperature and a low temperature. Accordingly, data indicating that the temperature at that given spot is outside of the normal range may be predictive of a pre-ulcer **14** or an ulcer **12** at that location.

[0091] Some embodiments may use machine learning and advanced filtering techniques to ascertain risks and predictions, and to make the comparisons. More specifically, advanced statistical models may be applied to estimate the current status and health of the patient's feet **10**, and to make predictions about future changes in foot health. State estimation models, such as a switching Kalman filters, can process data as they become available and update their estimate of the current status of the user's feet **10** in real-time. The statistical models can combine both expert knowledge based on clinical experience, and published research (e.g., specifying which variables and factors should be included in the models) with real data gathered and analyzed from users. This permits models to be trained and optimized based on a variety of performance measures.

[0092] Models can be continually improved as additional data is gathered, and updated to reflect state-of-the-art clinical research. The models also can be designed to take into account a variety of potentially confounding factors, such as physical activity (e.g., running), environmental conditions (e.g., a cold floor), personal baselines, past injuries, predisposition to developing problems, and problems developing in other regions (e.g., a rise in temperature recorded by a sensor **26** may be due to an ulcer **12** developing in a neighboring region measured by a different sensor). In addition to using these models for delivering real-time analysis of users, they also may be used off-line to detect significant patterns in large archives of historical data. For example, a large rise above baseline temperature during a period of inactivity may precede the development of an ulcer **12**.

[0093] Alternative embodiments may configure the pattern recognition system **68** and analyzer **70** to perform other processes that identify risk and emergence, as well as assist in tracking the progressions ulcers **12** and pre-ulcers **14**. For example, if there is no ambient temperature data from a thermogram prior to the patient's use of the platform **16**, then some embodiments may apply an Otsu filter (or other filter) first to the high resolution thermogram to identify regions with large temperature deviations from ambient. The characteristics of these regions (length, width, mean temperature, etc. . . .) then may be statistically compared to known distributions of foot characteristics to identify and isolate feet **10**. The right foot thermogram may be mirrored and an edge-alignment algorithm can be employed to standardize the data for hotspot identification.

[0094] Two conditions can be evaluated independently for hotspot identification. The first condition evaluates to true when a spatially-localized contralateral thermal asymmetry exceeds a pre-determined temperature threshold for a given duration. The second condition evaluates to true when a spatially-localized ipsilateral thermal deviation between temporally successive scans exceeds a pre-determined temperature threshold for a given duration. The appropriate durations and thermal thresholds can be determined from literature review or through application of machine learning techniques to data from observational studies. In the latter case, a support vector machine or another robust classifier can be applied to outcome data from the observational study to determine appropriate temperature thresholds and durations to achieve a desired balance between sensitivity and specificity.

[0095] Illustrative embodiments have a set of prescribed patterns against which the pattern recognition system **68** and analyzer **70** compare to determine foot health. Accordingly, discussion of specific techniques above are illustrative of any of a number of different techniques that may be used and thus, are not intended to limit all embodiments of the invention.

[0096] Some embodiments discussed above generally check for similar patterns across the entire foot. Alternative embodiments, however, check for different patterns at different points of the foot/feet. Such alternative embodiments apply both to various embodiments that use thermograms, and to various embodiments that do not use thermograms. The latter embodiments may simply use the discrete temperature data value(s) produced by the temperature sensors **26**.

[0097] Specifically, such embodiments may use non-uniform temperature thresholds to evaluate risk and for determining what these thresholds ought to be to support monitoring with a target sensitivity and specificity. The temperature thresholds may depend on the anatomical location of the temperature difference in question, as well as the temperature differences preceding the most recent measurement chronologically. This permits more granular interpretation of risk into the monitoring.

[0098] For example, the contralateral asymmetry threshold for determining if the foot presents a pattern indicative of inflammation may be at least 2.2 degrees C. at the midfoot, but at least 3.0 degrees at the hallux. In other words, this step may determine if the difference in temperature between two contralateral points/locations at the midfoot is more than 2.2 degrees. At the same time, this step may determine if the difference in temperature difference between two contralateral points/locations at the hallux is more than 3.0 degrees.

[0099] Accordingly, using either or both the discrete temperature values or a thermogram, different points on the foot can be compared to one of a plurality of different prescribed values—the prescribed values are selected based on the location. More generally, both contralateral foot temperatures may be considered as inputs into a prescribed function (in this example, a difference function), and the output of that prescribed function is compared against one of a plurality of different predetermined values. In the example above, 2.2 and 3.0 are two of the different predetermined values. As discussed below, the result of this comparison indicates the emergence of an ulcer or pre-ulcer. Accordingly, in this example, the predetermined value is selected for comparison as a function of the location being analyzed.

[0100] Alternatively, the temperature at any given anatomical point may be compared, using a function as noted above, to the mean foot temperature. For example, the actual temperature at a given point can be subtracted from the mean foot temperature, and then compared to one of the plurality of different predetermined values. Yet other embodiments may compare the temperatures at two different non-contralateral point (using a prescribed function) against one of the plurality of different predetermined values. Again, in this latter case, the threshold for determining if the foot presents a pattern indicative of inflammation also may be unique for each anatomical location or area. Accordingly, such alternative embodiments may have a plurality of different thresholds (e.g., 2.2 degrees C., 3.0 degrees C.) against which to compare temperature values.

[0101] Other patterns, as discussed previously, may be evaluated over the foot in the same way with unique sensitivities depending on the anatomical location being evaluated. The evaluation may also include a combination of these patterns with each anatomical location weighted differently in a generalizable mathematical model such as W1T1+W2T2+ . . . +WnTn, where Wn is the weight of the temperature pattern at location "n" and Tn is the magnitude of the temperature pattern at location "n". Those skilled in the art will understand that temperature patterns over the foot may be combined in various mathematical forms to perform useful interpretations of foot temperature data, including non-linear transforms of the foot data from disparate anatomical locations, dates, and times, and that the above formula is an example only.

[0102] Indeed, in addition to contralateral locations and different locations of the one or more feet, illustrative embodiments also apply to ipsilateral foot locations. For example, one may compare the difference in temperature over time of one location on the same foot (e.g., the mid-foot) to a predetermined value of 2.2 degrees C. In contrast, the same embodiment may compare the difference in temperature over time of a different location on the same foot (e.g., the hallux) to a predetermined value of 3.0 degrees C. Also, like other embodiments above, the difference is but an example of one type of prescribed function. Those skilled in the art may use other formulas to detect patterns. It should be noted that the predetermined values need not be in units of temperature. For example, the comparison function may calculate the ratio of temperatures for which the resulting value would be unit-less.

[0103] Various embodiments that use the different, anatomically dependent threshold values for comparison preferably have information indicating the position of the foot and thus, the specific locations to measure and compare. For example, such embodiments are configured to recognize the difference between the ball of the foot and the hallux. Various embodiments using the thermograms, after orienting, can identify the specific regions based on the foot shape and other information. Various embodiments that do not use the thermograms may use similar techniques to orient the foot/feet, but without the data between the sensors. Such embodiments can make approximations on the different locations based on the received discrete temperature data value from a region determined to be nearest the area of interest.

[0104] Whether using thermograms or discrete temperature data values, the output of this analysis can be processed to produce risk summaries and scores that can be displayed to various users to trigger alerts and suggest the need for intervention. Among other things, state estimation models can simulate potential changes in the user's foot **10** and assess the likelihood of complications in the future. Moreover, these models can be combined with predictive models, such as linear logistic regression models and support vector machines, which can integrate a large volume and variety of current and historical data, including significant patterns discovered during off-line analysis. This may be used to forecast whether the user is likely to develop problems within a given timeframe. The predictions of likelihood can be processed into risk scores, which also can be displayed by both users and other third parties. These scores and displays are discussed in greater detail below.

[0105] To those ends, the process continues to step **708**, which generates output information relating to the health of the foot **10**. Specifically, at this stage in the process, the analysis engine **46** has generated the relevant data to make a number of conclusions and assessments, in the form of output information, relating to the health of the foot **10**. Among other things, those assessments may include the risk of an ulcer **12** emerging anywhere on the foot **10**, or at a particular location on the foot **10**.

[0106] For example, if the temperature difference between two contralateral locations on the mid-foot exceeds 2.2 degrees C., then the output information may indicate the emergence of an ulcer or pre-ulcer. However, if the temperature difference between two contralateral locations on the hallux is 2.5 degrees (assuming a 3.0 degree C. threshold for the hallux), then the output information may indicate no emergence of an ulcer or pre-ulcer. For the hallux in that example, the output information would indicate emergence of an ulcer or pre-ulcer if the temperature difference exceeded 3.0 degrees.

[0107] Moreover, the magnitude of the difference may indicate the relative risk of for the emergence of an ulcer or pre-ulcer on at least one foot. For example, a higher temperature difference may indicate a more serious risk of the emergence of an ulcer than a lower temperature difference. Continuing with this example, a temperature difference of 4 degrees C. for the hallux may indicate a higher risk of an ulcer or pre-ulcer at that location than a temperature difference of 3.1 degrees C. for that same location. Accordingly, the output information may include risk information indicating the risk of the emergence of an ulcer or a pre-ulcer based on the magnitude of the difference.

[0108] This risk may be identified on a scale from no risk to maximum risk. Among other things, that risk may be based on the magnitude of the difference noted above. FIG. **11**A shows one example of the output information in a visual format with a scale ranking the risk of ulcer emergence. The scale in this example visually displays de-identified patients (i.e., Patient A to Patient **2**) as having a certain risk level of developing the foot ulcer **12**. The "Risk Level" column shows one way of graphically displaying the output information, in which more rectangles indicate a higher risk of ulcer **12**. Specifically, in this example, a single rectangle may indicate minimal or no risk, while rectangles filling the entire length of that table entry may indicate a maximum risk or fully emerged ulcer **12**. Selection of a certain patient may produce an image of the foot **10** with a sliding bar showing the history of that patient's foot **10**. FIG. **11**B schematically shows a similar output table in which the risk level is characterized by a percentage from zero to hundred percent within some time frame (e.g., days). Patient C is bolded in this example due to their **80** percent risk of the emergence of an ulcer **12**.

[0109] The output table thus may provide the caregiver or healthcare provider with information, such as the fact that Patient B has a **90** percent probability that he/she will develop a foot ulcer **12** in the next **4-5** days. To assist in making clinical treatment decisions, the clinician also may access the patient's history file to view the raw data.

[0110] Other embodiments produce output information indicating the emergence of a pre-ulcer **14** at some spot on the foot **10**. As known by those skilled in the art, a pre-ulcer **14** may be considered to be formed when tissue in the foot **10** is no longer normal, but it has not ruptured the top layer of skin. Accordingly, a pre-ulcer **14** is internal to the foot **10**. More specifically, tissue in a specific region of the foot **10** may not be receiving adequate blood supply and thus, may need more blood. When it does not receive an adequate supply of blood, it may become inflamed and subsequently, become necrotic (i.e., death of the tissue). This creates a weakness or tenderness in that region of the foot **10**. Accordingly, a callous or some event may accelerate a breakdown of the tissue, which ultimately may rupture the pre-ulcer **14** to form an ulcer **12**.

[0111] Illustrative embodiments may detect the emergence of a pre-ulcer **14** in any of a number of manners described above. For example, the system may compare temperature readings to those of prior thermograms, such as the running average of the temperature at a given location, the running average (or weighted average) of foot temperature, and/or the current average temperature of the foot (e.g., an average of the discrete temperature data values of the most recent reading). The average (e.g., the weighted average) may be either or both a spatial or temporal average. This comparison may show an elevated temperature at that spot, thus signaling the emergence of a new pre-ulcer **14**. In more extreme cases, this may indicate the actual emergence of a new ulcer **12**.

[0112] The emergence or detection of a pre-ulcer **14** can trigger a number of other preventative treatments that may eliminate or significantly reduce the likelihood of the ultimate emergence of an ulcer **12**. To that end, after learning about a pre-ulcer **14**, some embodiments monitor the progression of the pre-ulcer **14**. Preferably, the pre-ulcer **14** is monitored during treatment in an effort to heal the area, thus avoiding the emergence of an ulcer **12**. For example, the caregiver may compare each day's thermogram to prior thermograms, thus analyzing the most up to date state of the pre-ulcer **14**. In favorable circumstances, during a treatment regimen, this comparison/monitoring shows a continuous improvement of the pre-ulcer **14**, indicating that the pre-ulcer **14** is healing. The output information therefore can have current and/or past data relating to the pre-ulcer **14**, and the risk that it poses for the emergence of an ulcer **12**.

[0113] Sometimes, patients may not even realize that they have an ulcer **12** until it has become seriously infected. For example, if the patient undesirably does not use the foot monitoring system for a long time, he/she may already have developed an ulcer **12**. The patient therefore may step on the platform **16** and the platform **16** may produce output information indicating the emergence of an ulcer **12**. To that end, the analyzer **70** may have prior baseline thermogram (i.e., data) relating to this patient's foot **10** (showing no ulcer), and make a comparison against that baseline data to determine the emergence of an actual ulcer **12**. In cases where the data is questionable about whether it is an ulcer **12** or a pre-ulcer **14**, the caregiver and/or patient nevertheless may be notified of the higher risk region of the foot **10** which, upon even a cursory visual inspection, should immediately reveal the emergence of an ulcer **12**.

[0114] The process concludes at step **710**, in which the process (optionally) manually or automatically notifies the relevant people about the health of the foot **10**. These notifications or messages (a type of "risk message") may be in any of a number of forms, such as a telephone call, a text message, e-mail, and data transmission, or other similar mechanism. For example, the system may forward an e-mail to a healthcare provider indicating that the right foot **10** of the patient is generally healthy, while the left foot **10** has a **20** percent risk of developing an ulcer **12**, and a pre-ulcer **14** also has emerged on a specified region. Armed with this information, the healthcare provider may take appropriate action, such as by directing the patient to stay off their feet **10**, use specialized footwear, soak their feet **10**, or immediately check into a hospital.

[0115] Illustrative embodiments thus obviate the inherent uncertainties of using a uniform temperature threshold for evaluating risk across one or more feet. The inventors recognized those inherent uncertainties by noticing that blood perfusion, tissue density, epidermal thickness, and proximity to bone vary significantly over the plantar surface over the foot, and each of these factors can impact the thermodynamics that govern the temperature rise in tissue undergoing an inflammatory response. For example, as suggested above, toes typically have much lower thermal mass than arches due the fact that there is less tissue volume and larger exposed skin area-to-volume in the toes. Additionally, toes are more distal from the arteries that supply blood to the foot than arches, heels, or forefeet.

[0116] The inventors also recognized that different regions of the foot are subject to more measurement error using conventional, commercially-available thermometric devices. This can result in noise that produces false positives or false negatives if not accounted for using non-uniform temperature thresholds.

[0117] There are also output issues when using temporally uniform temperature thresholds. For example, a very large temperature difference one day may be indicative of a problem whether or not it is followed by a second large temperature asymmetry. Alternatively, many consecutive temperature differences that are higher than average in a given population, but still less than the conventional 2.2 degrees Celsius threshold, may still warrant medical attention and suggest that a patient is at elevated risk. Accordingly, some populations my benefit from higher or lower thresholds at certain points on their foot/feet.

[0118] Illustrative embodiments substantially mitigate these inventor recognized problems by using variable temperature thresholds across the foot/feet.

[0119] Various embodiments of the invention may be implemented at least in part in any conventional computer programming language. For example, some embodiments may be implemented in a procedural programming language (e.g., "C"), or in an object oriented programming language (e.g., "C++"). Other embodiments of the invention may be implemented as preprogrammed hardware elements (e.g., application specific integrated circuits, FPGAs, and digital signal processors), or other related components.

[0120] In an alternative embodiment, the disclosed apparatus and methods (e.g., see the various flow charts described above) may be implemented as a computer program product (or in a computer process) for use with a computer system. Such implementation may include a series of computer instructions fixed either on a tangible medium, such as a computer readable medium (e.g., a diskette, CD-ROM, ROM, or fixed disk) or transmittable to a computer system, via a modem or other interface device, such as a communications adapter connected to a network over a medium.

[0121] The medium may be either a tangible medium (e.g., optical or analog communications lines) or a medium implemented with wireless techniques (e.g., WIFI, microwave, infrared or other transmission techniques). The medium also may be a non-transient medium. The series of computer instructions can embody all or part of the functionality previously described herein with respect to the system. The processes described herein are merely exemplary and it is understood that various alternatives, mathematical equivalents, or derivations thereof fall within the scope of the present invention.

[0122] Those skilled in the art should appreciate that such computer instructions can be written in a number of programming languages for use with many computer architectures or operating systems. Furthermore, such instructions may be stored in any memory device, such as semiconductor, magnetic, optical or other memory devices, and may be transmitted using any communications technology, such as optical, infrared, microwave, or other transmission technologies.

[0123] Among other ways, such a computer program product may be distributed as a removable medium with accompanying printed or electronic documentation (e.g., shrink wrapped software), preloaded with a computer system (e.g., on system ROM or fixed disk), or distributed from a server or electronic bulletin board over the larger network **44** (e.g., the Internet or World Wide Web). Of course, some embodiments of the invention may be implemented as a combination of both software (e.g., a computer program product) and hardware. Still other embodiments of the invention are implemented as entirely hardware, or entirely software.

[0124] Although the above discussion discloses various exemplary embodiments of the invention, it should be apparent that those skilled in the art can make various modifications that will achieve some of the advantages of the invention without departing from the true scope of the invention.

What is claimed is:

1. A method of determining the emergence of an ulcer or a pre-ulcer on at least one foot of a patient, the method comprising:

providing one or more processors;

providing a modality for receiving at least one foot, the modality 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 last one foot, the plurality of discrete temperature data values representing temperatures at different locations of the at least one foot;

comparing, using a prescribed function, at least one of the plurality of discrete temperature data values to one of a plurality of different predetermined values, the predetermined values being different for at least two different locations of the at least one foot; and

producing, by at least one of the processors, output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a function of said comparing.

2. The method as defined by claim **1** wherein the prescribed function subtracts one of the discrete temperature data values from another temperature value of the at least one foot to produce a difference value,

further wherein said comparing comprises comparing the difference value with one of the different predetermined values.

3. The method as defined by claim **2** wherein said producing comprises producing output information indicating the emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is greater than the predetermined value.

4. The method as defined by claim **2** wherein said producing comprises producing output information indicating no emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is not greater than the predetermined value.

5. The method as defined by claim **1** wherein the prescribed function comprises an average or a weighted average of the plurality of discrete temperature data values.

6. The method as defined by claim **1** wherein said comparing includes using discrete temperature data values at corresponding contralateral foot locations of a patient's two feet in the prescribed function.

7. The method as defined by claim **1** wherein the plurality of discrete temperature data values includes a first discrete temperature data value representing a first location on a patient's left foot, the plurality of discrete temperature data values including a second temperature data value representing a second location on the patient's right foot, the first and second locations being contralateral foot locations,

the prescribed function using both the first and second temperature data values to generate a function output value, said comparing using the function output value to compare against one of the plurality of predetermined values.

8. The method as defined by claim **1** wherein said plurality of discrete temperature data values include an earlier temperature data value and a later temperature data value, both the earlier and later temperature data values representing the same location of the same foot at different times,

said comparing including using the earlier and later discrete temperature data values in the prescribed function.

9. The method as defined by claim **1** wherein the modality includes an open platform.

10. The method as defined by claim **1** further comprising:

forming, by at least one of the processors, at least one thermogram of the at least one foot 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; and

said comparing comprising comparing, using the prescribed function and the at least one thermogram, temperatures at first and second different locations on the at least one foot to respective different predetermined values of the plurality of different predetermined values.

11. The method as defined by claim **1** wherein the output information includes risk information indicating the risk for the emergence of an ulcer or a pre-ulcer on the at least one foot as a function of said comparing,

said comparing producing a comparison value having a magnitude, the risk information being a function of the magnitude.

12. An apparatus for determining the emergence of an ulcer or a pre-ulcer on at least one foot of a patient, the apparatus comprising:

one or more processors;

a modality for receiving at least one foot, the modality having a plurality of temperature sensors, the plurality of temperature sensors configured to generate a plurality of discrete temperature data values after receipt of the at last one foot, the plurality of discrete temperature data values representing temperatures at different locations of the at least one foot;

a comparator operatively coupled with the plurality of temperature sensors, the comparator being configured to compare, using a prescribed function, at least one of the plurality of discrete temperature data values to one of a plurality of different predetermined values, the predetermined values being different for at least two different locations of the at least one foot; and

an analyzer operatively coupled with the comparator, the analyzer being configured to produce output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a function of the comparison of the comparator.

13. The apparatus as defined by claim **12** wherein the prescribed function subtracts one of the discrete temperature data values from another temperature value of the at least one foot to produce a difference value,

further wherein the comparator is configured to compare the difference value with one of the different predetermined values.

14. The apparatus as defined by claim **13** wherein the analyzer is configured to produce output information indicating the emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is greater than the predetermined value.

15. The apparatus as defined by claim **13** wherein the analyzer is configured to produce output information indicating no emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is not greater than the predetermined value.

16. The apparatus as defined by claim **12** wherein the prescribed function comprises an average or a weighted average of the plurality of discrete temperature data values.

17. The apparatus as defined by claim 12 wherein the comparator is configured to use the discrete temperature data values at corresponding contralateral foot locations of a patient's two feet in the prescribed function.

18. The apparatus as defined by claim 12 wherein said plurality of discrete temperature data values include an earlier temperature data value and a later temperature data value, both the earlier and later temperature data values representing the same location of the same foot at different times,

the comparator being configured to use the earlier and later discrete temperature data values in the prescribed function.

19. The apparatus as defined by claim 12 wherein the modality includes an open platform.

20. The apparatus as defined by claim 12 wherein the output information includes risk information indicating the risk for the emergence of an ulcer or a pre-ulcer on the at least one foot as a function of said comparing by the comparator,

the comparator comparison producing a comparison value having a magnitude, the risk information being a function of the magnitude.

21. A computer program product for determining the emergence of an ulcer or a pre-ulcer on at least one foot of a patient, the computer program product comprising a tangible, non-transient computer usable medium having computer readable program code thereon, the computer readable program code comprising:

program code for receiving a plurality of discrete temperature data values from a modality having a plurality of temperature sensors after receipt of at least one foot on the modality, the plurality of discrete temperature data values representing temperatures at different locations of the at least one foot;

program code for comparing, using a prescribed function, at least one of the plurality of discrete temperature data values to one of a plurality of different predetermined values, the predetermined values being different for at least two different locations of the at least one foot; and

program code for producing, by at least one of the processors, output information indicating an emergence of an ulcer or a pre-ulcer on the at least one foot as a function of said comparing.

22. The computer program product as defined by claim 21 wherein the prescribed function subtracts one of the discrete temperature data values from another temperature value of the at least one foot to produce a difference value,

further wherein said comparing comprises comparing the difference value with one of the different predetermined values.

23. The computer program product as defined by claim 22 wherein the program code for producing comprises program code for producing output information indicating the emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is greater than the predetermined value.

24. The computer program product as defined by claim 22 wherein the program code for producing comprises program code for producing output information indicating no emergence of an ulcer or pre-ulcer on the at least one foot if the difference value is not greater than the predetermined value.

25. The computer program product as defined by claim 21 wherein the prescribed function comprises an average or a weighted average of the plurality of discrete temperature data values.

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摘要(译)

一种方法确定患者的至少一只脚上的溃疡或前溃疡的出现提供了一个或多个处理器和用于接收至少一只脚的模态。该方法使用多个温度传感器在接收到最后一只脚之后生成离散的温度数据值。多个离散温度数据值代表至少一只脚的不同位置处的温度。接下来，该方法使用规定的函数将每个离散温度数据值与多个不同的预定值中的一个进行比较。预定值对于至少一只脚的至少两个不同位置是不同的。作为比较的结果，该方法然后产生指示至少一只脚上出现溃疡或溃疡前的输出信息。