

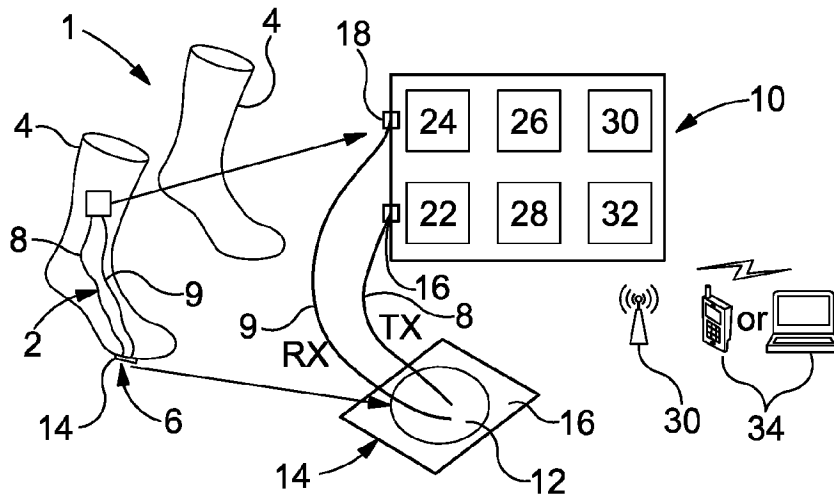


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(54) **Title:** CAPILLARY REFILL MEASUREMENT



**Figure 1**

(57) **Abstract:** A capillary refill measurement apparatus (1), comprising a support element (14) configured to receive the weight of a user through their foot, a light source (22) for illuminating a region of the foot that exerts weight onto the support element (14), a light detector (24) arranged to receive light from the illuminated region (36) of the foot and generate an output based on the received light, and a processor (26) configured to determine a capillary refill rate from the output of the light detector (24) when the user adjusts the amount of weight received by the support element (14).

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## Capillary Refill Measurement

The present invention relates to a method and apparatus for measuring capillary refill time. More specifically, the invention relates to measuring capillary refill time at a  
5 foot.

Individuals with diabetes and vascular disease have an increased risk of developing foot ulcers and complications. Such complications can be severe and ultimately may result in amputation. Disease of the foot in diabetes represents a major health risk and  
10 a source of very considerable cost and suffering. Over 80% of people who lose a leg in diabetes initially present with a foot ulcer (Pecoraro et al. Diabetes Care 13:513-521, 1990). Major contributory risk factors for the development of foot ulcers and tissue breakdown are impaired peripheral bloodflow and peripheral neuropathy with the loss of ability to feel pain, temperature or pressure sensation in the feet and lower legs  
15 (Boulton et al. www.thelancet.com 366, 2005).

Foot ulceration affects approximately 15% of people with diabetes and can be difficult to treat: only two thirds heal in six months and the cost to the NHS in the UK is 2010-2011 was £650-750M (Kerr, Foot Care For People With Diabetes, www.diabetes.nhs.uk, 2011). The burden of care in relation to foot ulcers and related  
20 foot injuries is increasing with the ever increasing prevalence of Type 2 diabetes (Vamos et al, Diabetes care 33:2592-2597, 2010). It has been recently reported that approximately 100 amputations are performed each week in the UK, 85% of which are deemed to be avoidable (Holman et al. Diabetologia 2012).

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J. Spigulis et al (Wearable wireless photoplethysmography sensors, Biophotonics: Photonic Solutions for Better Health Care, Proc SPIE Vol. 6991, doi 10.1117/12.801966) discloses a photoplethysmography (PPG) sensor that may be integrated within a sock, hat or glove. The pulse wave transit time, determined by the  
30 time delay between a pulse at the hat and the glove, is used to infer blood pressure. The PPG sensor is not used to monitor circulation in the foot.

A method and apparatus that can provide prophylactic treatment of the type of foot injuries that may result from diabetes is desired, to reduce the cost and suffering  
35 associated with such injuries.

According to a first aspect of the invention, there is provided a capillary refill measurement apparatus, comprising a light source for illuminating a region of a foot of a user, a light detector arranged to receive light from the illuminated region of the foot and generate an output based on the received light, a processor and a support element. The support element is configured to receive the weight of a user acting through the foot. The processor is configured to determine a capillary refill rate from the output of the light detector when the user adjusts the amount of weight received by the support element. The illuminated region of the foot may be adjacent to the support element. The illuminated region of the foot may be a region of the foot that exerts weight onto the support platform when the support platform receives the weight of the user.

Such an apparatus enables monitoring of the circulation of the user's foot, for example whilst the user is walking around, so that any reduction in circulation may be detected early, and appropriate actions taken to prevent injury to the user's foot. The provision of a device that is for standing on enables rapid measurement of circulation as the user shifts their weight, in contrast to approaches in which an object is pressed into the user's skin using an externally applied force whilst the user is static. An apparatus that can support a user's weight at an illuminated region substantially simplifies determination of capillary refill at the user's feet, and monitoring it whilst the user moves around, for example, in daily use, may be better as a useful measurement in some circumstances.

The apparatus may further comprise a force or pressure transducer, configured to provide an output based on the amount of weight supported by the support element. The pressure transducer may allow the changes in light detected at the illuminated region to be corrected for the magnitude and/or duration of the pressure applied prior to capillary refill, thereby enhancing the accuracy of the measurement.

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The pressure transducer may comprise an electrically conductive woven fabric that changes impedance (e.g. changes resistance) in response to pressure. The use of an electrically conductive woven fabric simplifies the integration of a pressure sensor with a wearable item, enabling a low profile pressure sensor that is comfortable and unobtrusive.

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The apparatus may further comprise a temperature sensor configured to provide an output related to the temperature of the foot, when the apparatus is in use. Directly measuring the temperature of the foot near to the illuminated region (for example within 2cm) may provide optimal data for temperature correction of the capillary refill time.

When determining a capillary refill rate the processor may be responsive to at least one of a pressure on the support element and the temperature of the foot. Use of the temperature and pressure readings may enhance accuracy and consistency, enabling relevant comparisons to be made between capillary refill times measured under different conditions. The processor may be remote from the foot of the user.

The apparatus may comprise an illumination optical fibre for directing light from the light source to the illuminated region and a sensing optical fibre for directing light from the illuminated region to the light detector. Optical fibres enable a light source that is remote from the illuminated region to be used, improving the range of target applications for the device. Optical fibres can be integrated with a wearable item without compromising comfort because they are relatively thin and flexible.

The illumination optical fibre and/or the sensing optical fibre may comprise a stripped portion in which light is transmissible through a sidewall of the optical fibre.

A tip of the illumination optical fibre that is adjacent to the illuminated region may be at an angle of between  $25^\circ$  and  $180^\circ$ , or between  $25^\circ$  and  $155^\circ$  to a direction of a tip region of the sensing optical fibre that is adjacent to the illuminated region. The tip region of the illumination optical fibre may be at an angle of between  $75^\circ$  and  $105^\circ$  to the tip of the sensing optical fibre. The applicant has found that these angular ranges to reduce the change in detected light as a result of movement of the user. In these angular ranges, the fibres are said to be at  $0^\circ$  when they are end to end, and their axes are co-incident. When the fibres are side by side, parallel and facing in opposite directions, they are at an angle of  $180^\circ$ . Avoiding an end to end arrangement may be advantageous, because this arrangement may increase movement artefacts.

The illumination and/or sensing optical fibre may comprise or consist of a polymer optical fibre. Plastic optical fibres may be relatively low cost, with sufficient performance. A cladding of the optical fibre may comprise a fluorinated polymer. A core of the optical fibre may comprise PMMA (Poly(methyl methacrylate)) or a  
5 perfluorinated polymer (e.g. polyperfluorobutenylvinylether).

The illumination and sensing optical fibre may comprise a cladding and a core. A stripped portion may be a region from which cladding has been at least partially removed, such that light within the illumination fibre will more readily pass through a  
10 sidewall of the core. The surface of the core in the stripped portion may be roughened, in order to enhance the transmission of light through the sidewall of the core in the stripped portion.

The stripped portion may be formed by abrading the cladding of the illumination  
15 and/or sensing optical fibre. The core may also be at least partially abraded (for example to enhance surface roughness thereof).

A stripped portion of the illumination optical fibre may be arranged adjacent to a stripped portion of the sensing optical fibre. Light may thereby be coupled from the  
20 illuminating optical fibre to the sensing optical fibre via an adjacent foot.

The illumination and sensing optical fibre may be substantially parallel in the region of the stripped portions thereof.

25 The apparatus may comprise a sensing region, comprising an illumination optical fibre and a first and second sensing optical fibre arranged on either side of the illumination optical fibre. The sensing region may comprise stripped portions of the illumination optical fibre and stripped portions of the first and second sensing optical fibre.

30 The stripped portions of the illumination optical fibre and first and second optical fibre may be substantially parallel.

A length of the stripped portion may be 1mm to 15mm. The length of the stripped portion may be 5mm to 10mm.

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A spacing between adjacent stripped portions may be 0.5mm to 2mm. The spacing may be around 1mm.

5 The support element may comprise a fabric, such as a woven fabric. The use of fabric, simplifies the integration of a pressure sensor with a wearable item. At least one of the illumination and sensing optical fibre may be woven into the fabric of the support element. This minimises the impact of the illumination and sensing means on the comfort of the user.

10 The sensing optical fibre (or fibres) and the illumination optical fibre (or fibres) may be knitted in the fabric such that these optical fibres are substantially parallel.

The apparatus may comprise a wireless transmitter for transmitting information from the processor to a remote computer. Wirelessly transmitting data allows alerts to be sent to the user (or their healthcare professional) based on the data, without the need for connecting the apparatus to an external computer via a wired connection. For instance, the remote computer may determine that the capillary refill rate indicates a health problem, and may send a notification to the user to alert them of this. An application may be provided for a smartphone for receiving data from the apparatus, which is operable to generate an alert based on a predetermined threshold. The application may be configured to automatically forward notifications to third parties (such as a nurse or doctor) based on the capillary refill rate.

25 The apparatus may comprise a housing in which the light source, light detector and processor are disposed.

The housing may comprise a connector for removably coupling at least one of: the illumination and optical fibre to the light source and the sensing optical fibre to the light detector. Such an arrangement allows the housing to be re-used. The item comprising the support element may be disposable, and the housing re-usable, thereby minimising the cost of using the apparatus. The item comprising the support element may be tailored for a particular user's needs, for example being designed to fit a user's foot. The housing may be generic, and connectable to a tailored item comprising the support element.

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The housing may comprise a strap for mounting on an ankle of the user. This is a convenient way of supporting the housing in proximity to the foot.

5 The apparatus may be wearable by the user. A wearable device enables monitoring of circulation in the foot as the user is walking, and removes the need for a user to have to operate equipment that they do not already have with them. A wearable device can intermittently or regularly monitor health of circulation in a user's foot (for example at least once per day), and alert the user to any changes. For example, the user could be advised to take a break from walking. Alternatively, periods of inactivity in which  
10 no walking takes place could result in a prompt for the user to exercise in order to improve their general health.

The support element may comprise part of a sock. The support element may comprise part of an insole and/or part of a shoe.

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According to a second aspect of the invention, there is provided a weighing scale comprising the apparatus according to the first aspect. The scale comprises a platform for a user to stand on, and may include a display for displaying the weight of the user on the platform. The platform comprises the support element and the light source and  
20 the light detector are attached to the platform. Standing on scales may be part of a regular routine for many people and checking of circulation in their feet can be integrated into such a routine if apparatus capable of performing such a measurement is integrated with their scales. Scales typically include a display suitable for indicating the weight of the user, which may also be used to indicate the capillary refill time  
25 and/or to make recommendations for the user to follow to improve or maintain the health of their feet.

According to a third aspect of the invention, there is provided a method of determining a capillary refill rate comprising illuminating a region of a foot of a user,  
30 measuring light from the illuminated region as the user shifts their weight on the illuminated region, and determining a capillary refill time from the measured light.

The method may be performed using the apparatus according to the first or second aspect. The method may comprise comparing the capillary refill rate with a normal  
35 value of a capillary refill rate. The normal value of capillary refill rate may be taken

from an earlier time, or at a different spatial position, or on the opposite foot. The method may comprise sending an alert if the capillary refill rate deviates from the normal value. The method may comprise generating a recommendation to a user to change their behaviour based on the capillary refill time. The recommendation may be automatically generated. The recommendation may be communicated to a user's mobile phone or personal computer by the apparatus.

According to a fourth aspect of the invention, there is provided a capillary refill measurement apparatus, comprising a support element configured to receive the weight of a user through their foot, a light source for illuminating a region of the foot that exerts weight onto the support element, a light detector arranged to receive light from the illuminated region of the foot and generate an output based on the received light, wherein the output is suitable for performing a capillary refill measurement.

Optional features of the first and second aspect, and of the example embodiments described hereinafter, may be combined with the fourth aspect of the invention.

Embodiments of the invention will now be described, purely by way of example, with reference to the accompanying drawings, in which:

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Figure 1 is a schematic diagram of an apparatus according to an embodiment of the first aspect of the invention;

Figure 2 is a schematic of an example arrangement of sensing an illumination optical fibres;

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Figure 3 is a graph showing light intensity measured under a foot by apparatus according to an embodiment of the invention;

Figure 4 is a graph showing a single weight on, weight off, capillary refill cycle, measured under a foot by apparatus according to an embodiment of the invention;

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Figure 5 is a schematic diagram of an embodiment of the second aspect of the invention;

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Figure 6 is a schematic of a foot showing example illuminated regions;

Figure 7 is a flow diagram of a method of using the apparatus according to an embodiment;

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Figure 8 is a diagram of embodiments integrated with an insole and with a shoe.

Figure 9 is a schematic diagram of a sensing region defined by stripped portions of adjacent optical fibres;

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Figure 10 is a photograph of a sensing region defined by stripped portions of adjacent optical fibres;

Figure 11 is a graph of a capillary refill time for a warm foot measured using an apparatus according to an embodiment; and

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Figure 12 is a graph of a capillary refill time for a cold foot measured using an apparatus according to an embodiment.

20 Referring to Figure 1, a pair of socks 4 are shown. The right sock 4 comprises apparatus 1 according to an embodiment of the invention. The apparatus 1 comprises a housing 10, support element 14 and a pair of optical fibres 2. The pair of optical fibres 2 comprise an illumination optical fibre 8 and a sensing optical fibre 9.

25 In the housing 10 are disposed a light source 22, light detector 24, analog to digital converter 26, processor 28, power source 30 and wireless transmitter/transceiver 32. A light source connector 16 is provided for coupling a first end of the illumination optical fibre 8 to the light source 22. A light sensing connector 18 is provided for coupling a first end of the light sensing optical fibre 9 to the light detector 24.

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In this embodiment, the light source 22 is a light emitting diode (LED), but any suitable light source may be used (for instance a red light emitting diode, or some other type of light source). The light detector 22 is preferably a photodiode, but may be any suitable light sensor that provides the appropriate sensitivity and signal to noise ratio.

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The respective second ends of the illuminating and sensing fibres 8, 9 are positioned adjacent to the surface of the support element 14. The support element 14 is a portion of the sock 4 that, when the sock 4 is worn by a standing or walking user, bears weight from the user. The illuminating optical fibre 8 is arranged on the support element 14 so that light leaving the second end of the illuminating optical fibre 8 illuminates the region of the foot that is adjacent to the support element 14. The second end of the sensing optical fibre 9 is positioned to receive the light from the illuminated region of the foot, at least some of which will be absorbed by blood that is present in the capillaries near the skin. A different amount of blood in the capillaries will result in a different amount of light being received by the sensing fibre 9.

When the user changes the weight onto the support element 14 through the foot, for instance by shifting their weight, or by standing, blood may be squeezed from the capillaries, resulting in a change in the light received by the sensing fibre 9. The reduction in blood in the capillaries results in a higher light intensity received by the sensing fibre 9, which is detected by the light detector 24. When the user reduces the weight on the support element 14, blood will refill the capillaries adjacent to the illuminated region, and this will again change the light intensity received by the sensing fibre 9 and detected by the light detector 24.

The sensing and illuminating optical fibres 8, 9 are preferably integrated with the fabric of the sock 4, for example by stitching, knitting or weaving the fibres 8, 9 through the fabric of the sock 4. The integration of the optical fibres 8, 9 can take place during fabrication of the sock, or after. For example, the fibres 8, 9 can be stitched through the sock 4, or glued or taped to it.

In some embodiments there may be a plurality of illumination optical fibres 8 and/or a plurality of sensing optical fibres 9. In some embodiments the light source 22 may comprise a plurality of light emitting elements (such as LEDs). A plurality of illuminating optical fibres 9 may be coupled to a single light emitting element, or a light emitting element may be provided for each illuminating optical fibre 9. Similarly, more than one light detector 22 may be provided, each connected to a different sensing optical fibre 9.

The light source 22 may be controlled by the processor 28. The light source 22 may be modulated (e.g. under the control of the processor 28), and the output from the light detector 22 may be demodulated (for instance by the processor 28), which may improve signal to noise ratio.

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The signal from the light detector 24 is preferably provided to the processor 28 after conversion to a digital signal by an analog to digital converter (ADC) 26. The processor 28 may include the ADC 26, or the ADC 26 may be a separate part.

10 The power supply 30 is preferably a battery (e.g. a rechargeable battery) but may be a capacitor or any other device suitable for providing stored electrical energy to the other components within the housing 10.

The processor 28 is configured to communicate wirelessly, via the wireless  
15 transmitter/transceiver 32 and antenna 30, which may be a Bluetooth® or Zigbee® device. The processor 28 may thereby interface with an external computer 34, for instance a personal computer, smartphone or tablet. The interface with the external computer 34 may be one way, enabling upload of data from the processor 28, or may be two way, allowing the external computer to control, program or set preferences on  
20 the processor 28.

The support element 14 comprises a pressure sensor 12, configured to provide an output related to the amount of weight that is applied to the support element 14 by the user. The support element 14 may further comprise a temperature sensor 16 that  
25 detects the temperature of the region of the foot in contact with the support element 14. Both the pressure sensor 12 and the temperature sensor 16 provide their outputs to the processor 28, via the ADC 26. In some embodiments the temperature sensor is integrated with the support element 14. Alternatively, the temperature sensor may merely be close to the support element, for example within 1mm, 10mm, 20mm,  
30 30mm or 40mm of the support element 14.

The pressure sensor 12 is preferably integrated with the fabric of the sock 4. For instance, the pressure sensor 12 may be formed from a type of fabric that changes resistance when a load is applied thereto, such as the fabrics developed by Footfalls &  
35 Heartbeats Ltd of Auckland, New Zealand. Alternatively, the temperature sensor 16

may be a platinum wire type resistance based temperature sensor 16, a thermocouple, or a thermistor, and/or may be constructed from a fabric.

5 Wires connecting the pressure sensor 12 and temperature sensor 16 to the processor 28 are provided (not shown). The wires are preferably integrated with the fabric of the sock, for instance by stitching, knitting or weaving the wires through the fabric of the sock. A biasing and/or readout circuit may be used to derive measurements from the pressure sensor 12 and temperature sensor 16 (not shown).

10 Figure 2 shows an example arrangement of optical fibres 8, 9 at the support element 14 in more detail. In this embodiment the fibres 8, 9 are secured to the support element 14 using tape, rather than integrated with the support element 14 by weaving, knitting or stitching them in place. The fibres 8, 9 are secured to an outward facing external surface of the support element 14, with a hole being present in the support  
15 element 14 through which the skin is illuminated and light is received. In other embodiments the tips of the optical fibres 8, 9 that are adjacent to the support element 14 may be at an inward facing surface of the support element 14, so that they can illuminate and receive light without the need for a hole in the support element 14. In this example, the hole defines the region 36 of the foot to be illuminated. In an  
20 alternative arrangement, a portion of the sock 4 adjacent to the illuminated region 36 may be transparent, and the foot may be illuminated through the transparent portion.

There are a pair of illumination fibres 8, and a pair of sensing optical fibres 9. The applicant has found that it is advantageous to arrange the illumination and sensing  
25 optical fibres at an angle to each other, so as to reduce motion artefacts in the sensed light intensity. An angle of 90 degrees between the illumination and optical fibres 8, 9 has been used in this embodiment. The applicant has found this angle between the illumination and sensing optical fibres 8, 9 to be particularly advantageous for rejecting movement artefacts.

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The respective tips of the pair of illumination fibres 8 adjacent to the support element 14 are substantially parallel, and shine light at the illuminated region 36 from opposite directions. The respective tips of the pair of sensing optical fibres 9 are likewise substantially parallel, and respectively detect light scattered from the illuminated

region 36 in two opposite directions, these directions being at approximately 90 degrees to the tips of the illumination fibres 8.

The gap between the tips of the illumination fibres is approximately 3mm, and the gap  
5 between the tips of the sensing fibres is approximately 3mm. The ends of the sensing and illumination optical fibres are all substantially equidistant from the centre of the illuminated region 36, and are at a distance of approximately 1.5mm therefrom. In other embodiments the end of the sensing optical fibre (or fibres) may be further away, or closer to, the illuminated region than the end (or ends) of the illuminating  
10 optical fibre (or fibres).

In this embodiment the light source 22 is a green light emitting diode, and the light  
15 detector 24 is a photodiode. The processor 28 may be a low power embedded microcontroller.

The housing 10 may be miniaturised, and attached to a strap for mounting on the ankle  
of a user. Alternatively, the housing 10 may be attached to the fabric of the sock 2. The appropriate choice may depend on the size and weight of the housing 10 and the associated control electronics. The housing may be less than 2cm in maximum extent,  
20 and may have a bounding box of dimensions less than 2cm x 2cm x 8mm. The weight of the housing may be less than 100g, preferably less than 50g.

In some embodiments the power source may be external to the housing 10. The power  
source may comprise a major element of the size and weight

25 In some embodiments the connections 16, 18 between the optical fibres 8, 9 and the housing may be re-usable so that the housing 10 may be re-used with a plurality of socks 2 having integrated sensors. The sock 4 may be a low cost item and/or may be tailored to a specific user. The housing 10 and associated electronics may cost more,  
30 and may be generic and re-usable between different users. The wearable item (e.g. sock 4) may be free from electronic components, so that it is washable (e.g. by machine). The housing 10 may be waterproof and/or shockproof, and may, for example encapsulate the electronics (including the processor 26) in a polymeric and/or elastomeric material.

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Figures 9 and 10 show an alternative arrangement of optical fibres, in which an illumination fibre 8 and a first and second sensing fibre 9 are arranged substantially parallel to each other. The first and second sensing fibres 9 are positioned to either side of the illumination fibre 8.

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A sensing region 37 is defined by adjacent stripped portions 81, 91 of the illumination fibre 8 and first and second sensing fibres 9. In this example, the stripped portions 81, 91 are approximately 7mm long, and the spacing between stripped portion 81, 91 is approximately 1mm. At the stripped portions 81, 91, part of the cladding of the optical fibres 8, 9 has been removed so that light can pass through a sidewall of the fibre 8, 9. Light can pass through the side of stripped portion 81 of central illumination fibre 8 to illuminate an adjacent illuminated region of a foot. Light from the illuminated region is received in the sensing fibres 9 through the stripped regions 91.

15 A sidewall of a core of the optical fibre 8, 9 at the stripped portions 81, 91 may be roughened, in order to enhance transmission of light through the sidewall.

The same or a similar arrangement of light source and light detector to that described above can be used with this embodiment. The light from the first and second sensing fibres can be combined at a single detector, or a light detector can be provided for each sensing fibre 9.

20 Figure 10 shows a photograph of a fabric support element 14 having a sensing region 37 defined by stripped portions 81, 91 of three adjacent optical fibres. The stripped portions 81, 91 may conveniently be formed by abrading the cladding. This is particularly straightforward when the optical fibre is a polymer optical fibre. The stripped portions 81, 91 are at the surface of the fabric, so that the apparatus can readily be positioned to illuminate an adjacent region of skin if it is incorporated into a wearable item, such as a sock.

30 Figures 3 and 4 show traces obtained from an embodiment of the invention. The light intensity determined by the detector 24 is plotted against time as the user shifts the weight on their feet, for example by lifting and standing on a foot. At  $t=0$ , no load is being placed on the support element 14, and the light detector 24 provides a baseline reading corresponding with skin that is perfused with blood. At a later time 38, weight is placed on the support element 14 by the foot, and the blood is squeezed away from

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the surface capillaries by the pressure, resulting in an increase in intensity, up to a maximum 40, which may correspond with a maximum load condition on the support element 14.

5 The load on the support element 14, and the adjacent region of the foot, is subsequently removed, and the capillaries at the illuminated region 36 refill. An increase in light intensity is associated with unloading of the support element 14. The time it takes for the light intensity to return to the baseline perfused condition 42 from the loaded condition may be the capillary refill rate. The processor 28 is configured to  
10 determine the capillary refill rate from the output of the light detector 24. The processor may be responsive to the output of the pressure sensor 12 and temperature sensor 16 in determining the capillary refill rate. It is well known that the capillary refill rate may show a substantially linear temperature dependency, and the temperature of the illuminated region (or a region nearby) may thereby be used to  
15 provide temperature compensation (for example by means of a lookup table). The output of the pressure sensor 12 may be used to trigger the timing of the capillary refill measurement, and/or the capillary refill measurement may be corrected based on the magnitude and/or duration of loading prior to unloading.

20 Figures 11 and 12 show further example traces, obtained from an embodiment. Rather than using a foot, a finger was used in these examples to demonstrate the apparatus. In Figure 11, a warm finger is used, with a skin temperature of 29°C. The light intensity at t=42s corresponds with the finger pressing on a sensing region of the apparatus. The load is removed at the time indicated by 40, and the capillaries in the illuminated  
25 region adjacent to the sensing region refill. The light intensity returns to the baseline perfused condition at the time indicated by 42. The time difference between time 42 and time 40 is the capillary refill time, which is 1.2 seconds in this case. The pulse signal 101 is visible in the baseline perfused condition.

30 In Figure 12, the finger is cooled before the test (for instance in a cold water bath). The skin temperature for the data of Figure 12 is 19°C. This results in vasoconstriction, which increases the capillary refill time. In this graph, the capillary refill time is 2.5s.

Variations in capillary refill time resulting from temperature changes can clearly be detected by apparatus according to an embodiment.

In some embodiments, the processor 26 will perform a curve fitting analysis (for example based on regression), in order to fit a mathematical model to the curve, This may be a more robust measurement than simply timing the delay until the measured light intensity returns to a baseline. The use of a method that fits a mathematical function to the data may allow the capillary refill rate to be determined without needing the detected light to return to the baseline level. A capillary refill rate may be determined based on a plurality of load/unloading cycles (for example by averaging, or by any other appropriate technique, such as a maximum likelihood method).

A plurality of regions 36, 61, 62 of the foot may be illuminated, either by a plurality of light sources or by a single light source that is directed to each region (e.g. by optical fibres. There may be at least 3 illuminated regions, or at least 5 or 10 illuminated regions. The different regions may be positioned in different parts of the foot. For instance, where there are three illuminated regions, a first region may be on the heel, a second region may be near the ball of the foot (the first metatarsophalangeal joint), and a third region may be near a further metatarsophalangeal joint, for example the third such joint. In some embodiments there may be an array of sensors, which may be arranged in a grid pattern. Referring to Figure 6, a foot 60 is shown, illustrating multiple regions 61, 62 that may be illuminated in some aspects of the invention. At least one heel location 61 may be illuminated, along with at least one location 62 nearer to the toes.

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In an alternative embodiment the apparatus may comprise part of an insole 70 or shoe 80 (as shown in Figure 8. Where the apparatus is part of a shoe the housing 10 may for instance be within the sole of the shoe 80 (e.g. the heel). Such an arrangement may allow the light source 22 to directly illuminate the illuminated region of a foot within the shoe, with the need for a coupling means (such as an optical fibre). Similarly, the light detector 24 may be arranged to directly receive the light from the illuminated region. Alternatively, the light source 22 and light detector 24 may be coupled to the illuminated region 36 by a light guide, such as an optical fibre 2. An embodiment that is part of a shoe 80 may require the use of socks with a transparent region, or wearing of the shoe 80 without socks, so as to allow the foot to be illuminated.

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An apparatus comprised as part of an insole 70 may be inserted into a user's shoe, allowing them to continue to wear their normal shoes while the circulation in their feet is monitored. A low profile battery may be integrated with the insole 70, and the electronics from the housing 10 in the embodiment may be embedded within a foam material. The electronics may be formed on a flexible printed circuit board.

In some embodiments the apparatus is not wearable. In such device the support element 14 may comprise part of a platform 50 on which the user may stand, as shown in Figure 5. The platform 50 may comprise a plurality of support elements 14 for receiving the weight of the user. Each support element 14 may comprise at least one light source 22 and light detector 24, for illuminating at least one region of the user's foot on the support element 14. In such an arrangement the apparatus may be operable to determine a capillary refill rate when a user shifts their weight from one foot to the other without lifting their feet. A display 52 may be provided for displaying results derived from the capillary refill test, either in addition or as an alternative to transmitting data related to the capillary refill test. Pressure and temperature sensor 16s may be provided at each support element 14.

In some embodiments the apparatus is a weighing scale, and the display 52 is operable to indicate the weight of a user standing on the platform 50. The display 52 may be operable to provide instructions to the user in relation to performing a capillary refill test.

The scale may be configured to schedule circulation checks, so that checking of foot circulation becomes integrated with routine weight checking. A scheduled circulation check may be triggered by standing on the scale when a predetermine time has elapsed since the last circulation check. The display 52 may display instructions in relation to performing the circulation check, for example instructing the user how and when to shift their weight.

A method of determining capillary refill rate, and of improving health outcomes, in accordance with an embodiment of the invention, is shown in Figure 7. The method comprises putting on a wearable device at step 71. In some embodiments this step may instead involve standing on a platform. A region of the user's foot it illuminated in

step 72. Step 73 comprises and shifting weight on the support element. In step 74, the light from the illuminated region of the foot is measured during and after weight shift. In step 75 the capillary refill time is determined (e.g. by a processor), based on the measured light. In optional step 76 the capillary refill time may be transmitted (e.g. via Bluetooth® to a computer or smartphone). In optional step 77, a recommendation may be made for the user to change their behaviour based on the determined capillary refill rate. For example, the user's mobile phone (or other personal electronic device) may provide a notification that the user should take the weight off their feet, limit the amount of further walking/running they do, contact a health professional (such as a nurse or doctor), or provide some other message. The message need not be words: it could be an audio or visual or haptic signal.

These embodiments are non-limiting examples, and the scope of the invention is defined by the appended claims.

## Claims

1. A capillary refill measurement apparatus, comprising a support element configured to receive the weight of a user through their foot, a light source for illuminating a region of the foot that exerts weight onto the support element, a light detector arranged to receive light from the illuminated region of the foot and generate an output based on the received light, and a processor configured to determine a capillary refill rate from the output of the light detector when the user adjusts the amount of weight received by the support element.
2. The apparatus of claim 1, further comprising a force or pressure transducer, configured to provide an output based on the amount of weight received by the support element.
3. The apparatus of claim 2, wherein the pressure transducer comprises an electrically conductive woven fabric that changes impedance in response to pressure.
4. The apparatus of any preceding claim, further comprising a temperature sensor configured to provide an output related to the temperature of the foot, when the apparatus is in use.
5. The apparatus of any of claims 2 to 4, wherein the processor is configured to be responsive to at least one of a pressure on the support element and the temperature of the foot, when determining a capillary refill rate.
6. The apparatus of any preceding claim, comprising an illumination optical fibre for directing light from the light source to the illuminated region and a sensing optical fibre for directing light from the illuminated region to the light detector.
7. The apparatus of claim 7, wherein the illumination optical fibre and the sensing optical fibre each comprise a stripped portion in which light is transmissible through a sidewall of the optical fibre.

8. The apparatus of claim 7, wherein the apparatus comprises a first and second sensing optical fibre, with a stripped portion of the first and second optical fibre positioned on either side of a stripped portion of the illumination optical fibre.
9. The apparatus of claim 6, wherein a tip of the illumination optical fibre that is adjacent to the illuminated region is at an angle of between  $25^{\circ}$  and  $155^{\circ}$  to a tip of the sensing optical fibre that is adjacent to the illuminated region.
10. The apparatus of claim 9, wherein the tip of the illumination optical fibre is at an angle of between  $75^{\circ}$  and  $180^{\circ}$  to the tip of the sensing optical fibre.
11. The apparatus of any preceding claim, wherein the support element comprises a woven fabric.
12. The apparatus of claim 11, including the features of any of claims 6 to 10, wherein at least one of the illumination and sensing optical fibre are woven into the fabric of the support element.
13. The apparatus of any preceding claim, comprising a wireless transmitter for transmitting information from the processor to a remote computer.
14. The apparatus of any preceding claim, wherein the support element comprises a hole or transparent region through which the illuminated region may be illuminated.
15. The apparatus of any preceding claim, further comprising a power source for providing power to the light source, light detector and processor.
16. The apparatus of any preceding claim, the apparatus configured to illuminate a further region of the foot by the light source, the apparatus comprising a further detector is provided for receiving light from the further illuminated region.
17. The apparatus of claim 16, wherein the light source comprises a separate light emitting element for illuminating each illuminated region.

18. The apparatus of claim 16 or 17, wherein the apparatus is configured to illuminate a plurality of further illuminated regions, wherein each further illuminated region is illuminated by the light source, and the apparatus comprises a light detector for each illuminated region.

19. The apparatus of any preceding claim, comprising a housing in which the light source, light detector and processor are disposed.

20. The apparatus of claim 19, wherein the housing comprises a connector for removably coupling at least one of the illumination and optical fibre to the light source and the sensing optical fibre to the light detector.

21. The apparatus of claim 19 or 20, wherein the housing comprises a strap for mounting the housing on an ankle of the user.

22. The apparatus of any preceding claim, wherein the apparatus is wearable.

23. The apparatus of claim 22, wherein the support element comprises part of a sock.

24. The apparatus of claim 22, wherein the support element comprises part of an insole and/or part of a shoe.

25. The apparatus of any of claims 1 to 20, wherein the support element comprises part of a platform for a user to stand on.

26. A weighing scale comprising the apparatus of any of claims 1 to 20, the weighing scale comprising a platform for a user to stand on, wherein the platform comprises the support element and the light source and the light detector are attached to the platform.

27. A method of determining a capillary refill rate comprising illuminating a region of a foot of a user, measuring light from the illuminated region as the user

shifts their weight on the illuminated region, and determining a capillary refill time from the measured light.

28. The method of claim 27, wherein the method is performed using the apparatus of any of claims 1 to 26.

29. The method of claim 27 or 28, comprising comparing the capillary refill rate with a normal value of a capillary refill rate.

30. The method of any of claims 27 to 29, comprising sending an alert if the capillary refill rate deviates from the normal value.

31. The method of any of claims 27 to 30, comprising generating a recommendation to a user to change their behaviour based on the capillary refill time.

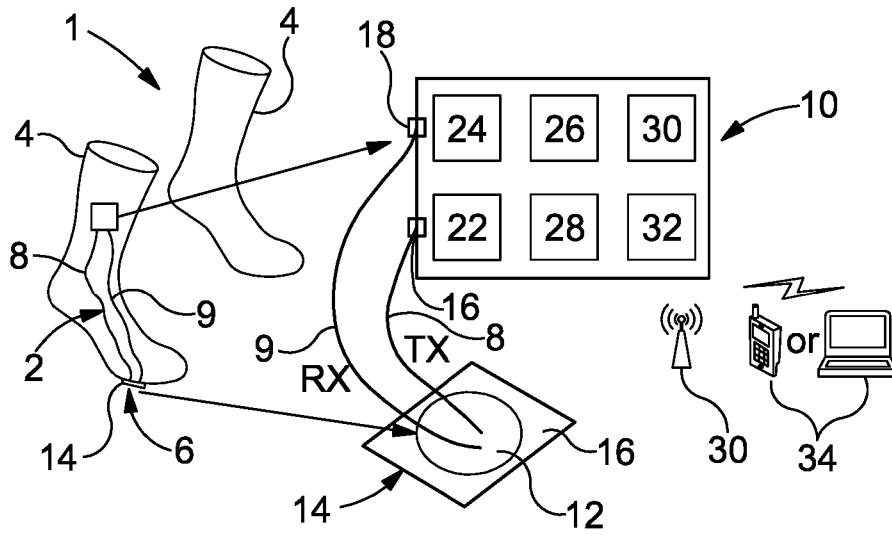


Figure 1

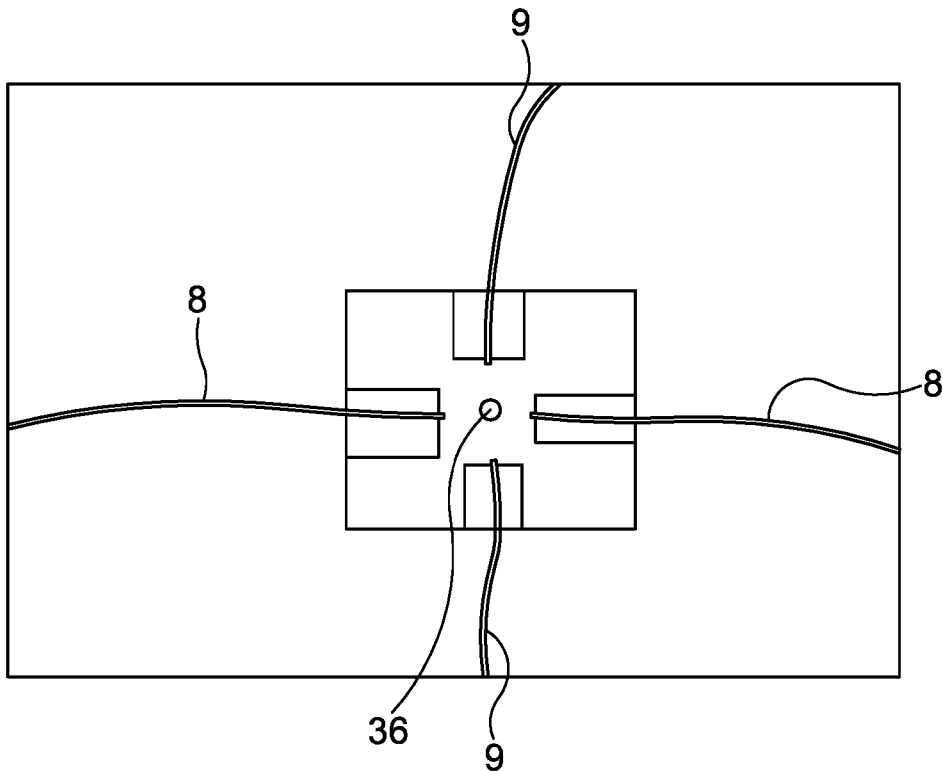


Figure 2

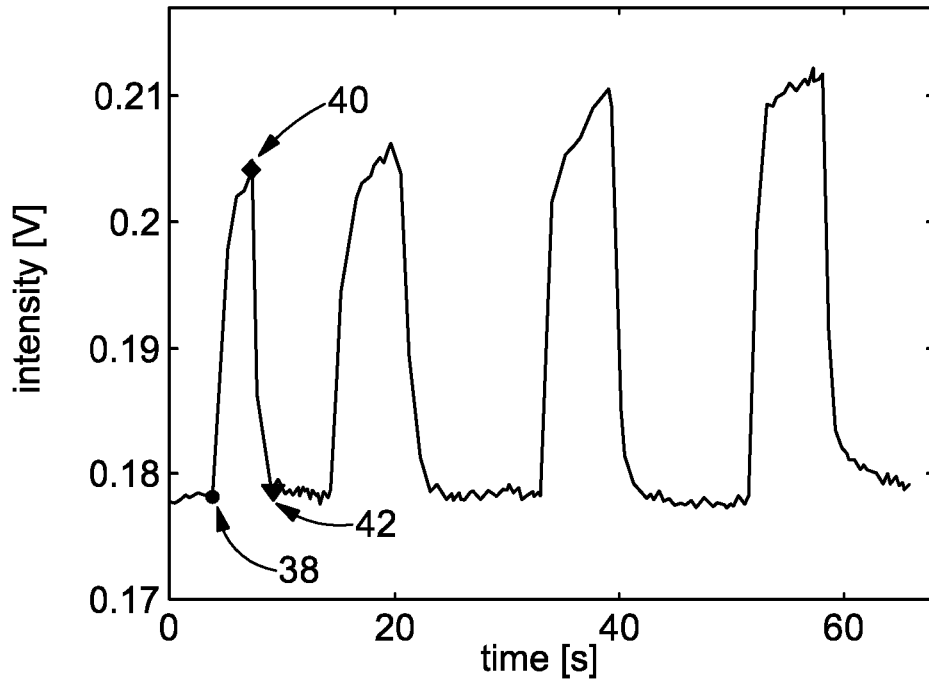


Figure 3

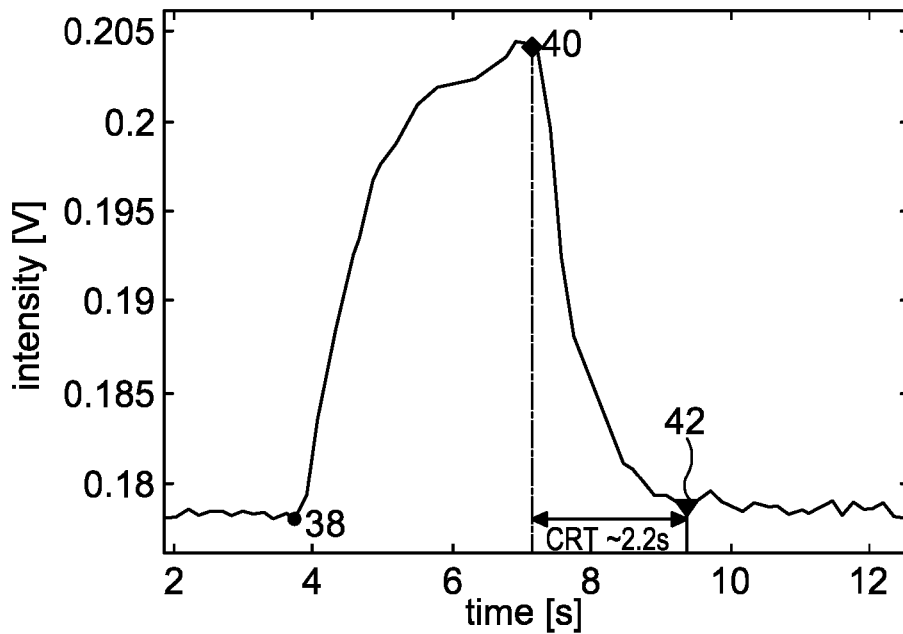


Figure 4

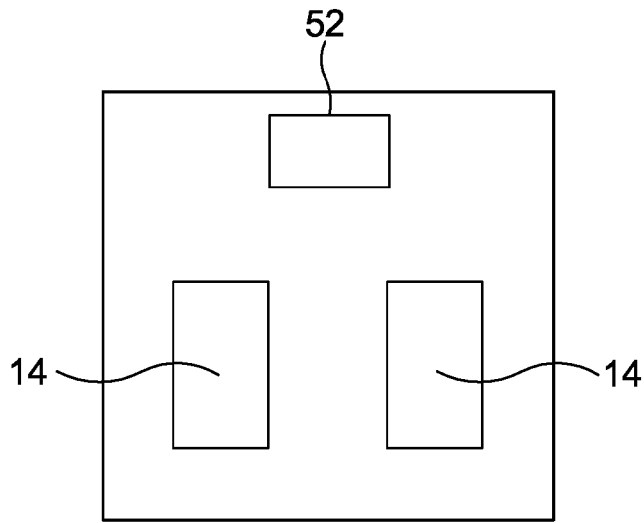


Figure 5

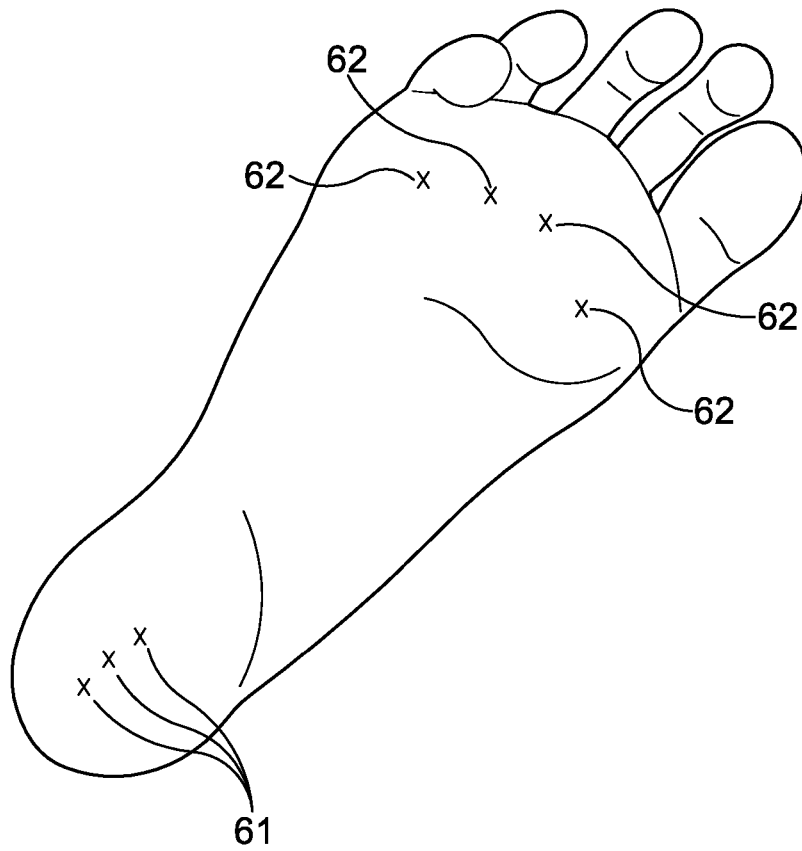


Figure 6

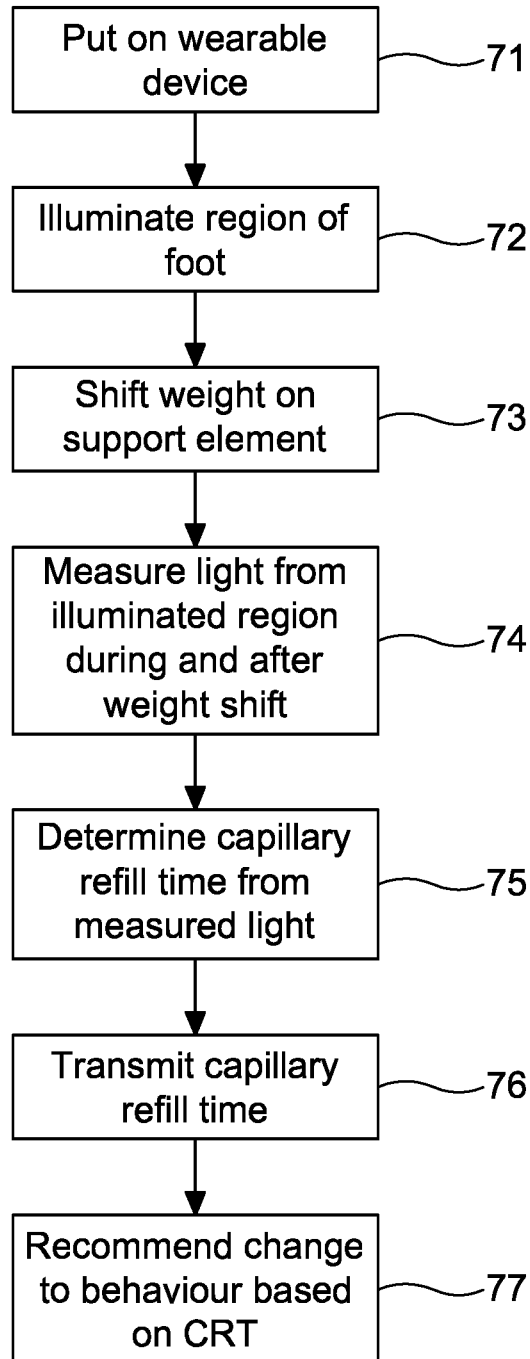


Figure 7

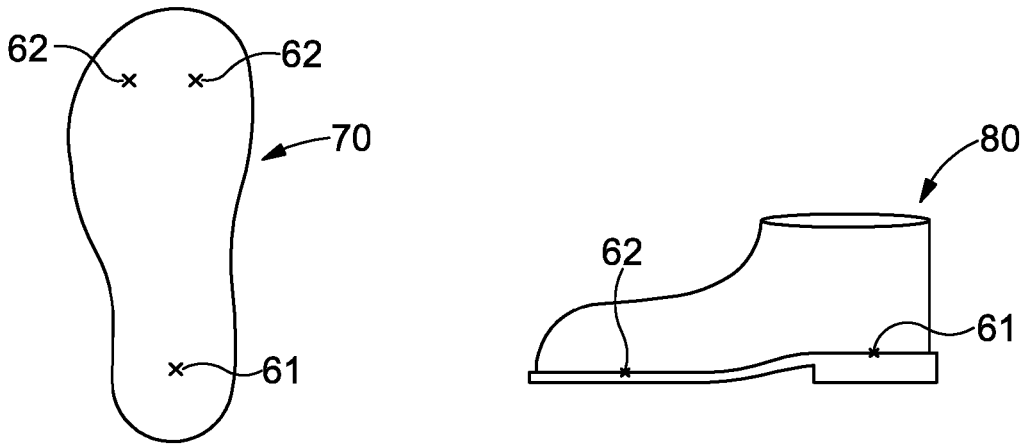


Figure 8

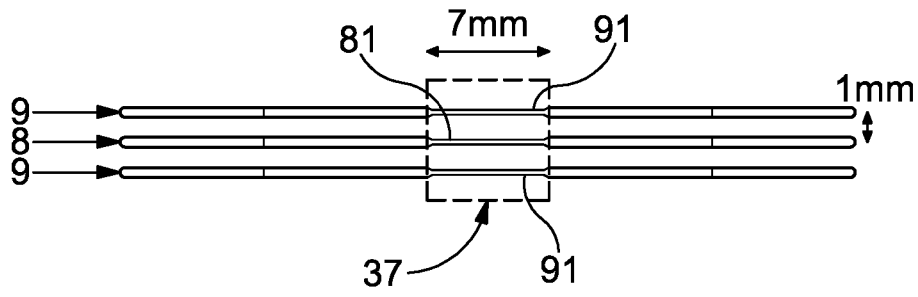


Figure 9

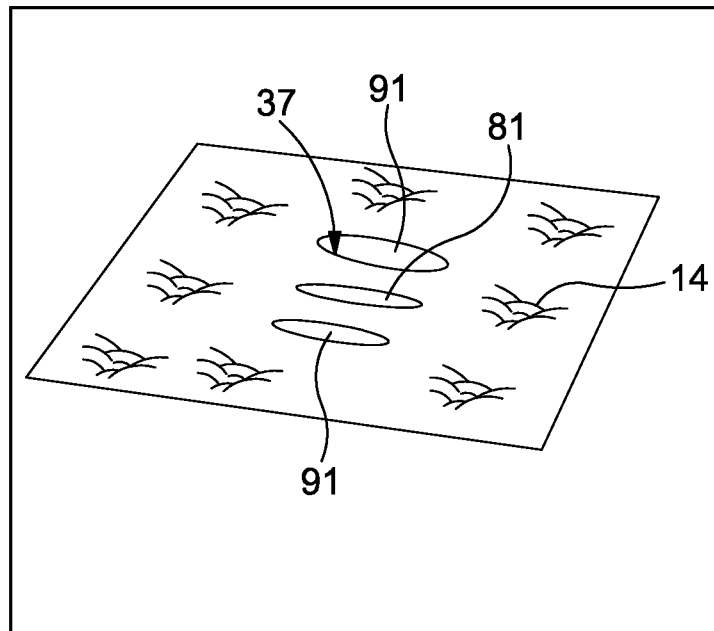


Figure 10

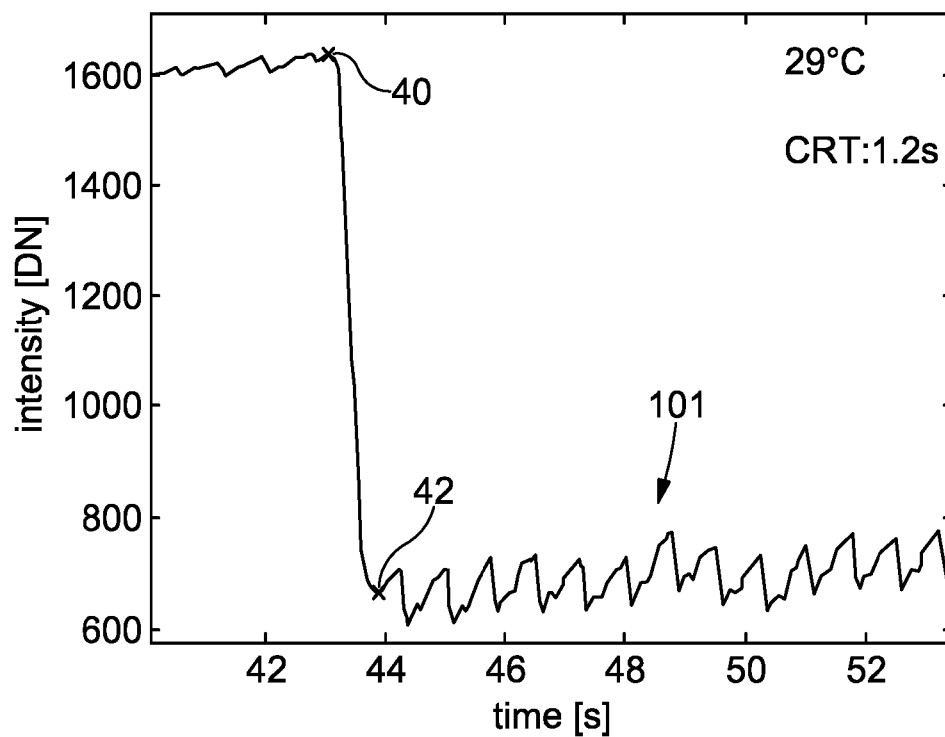


Figure 11

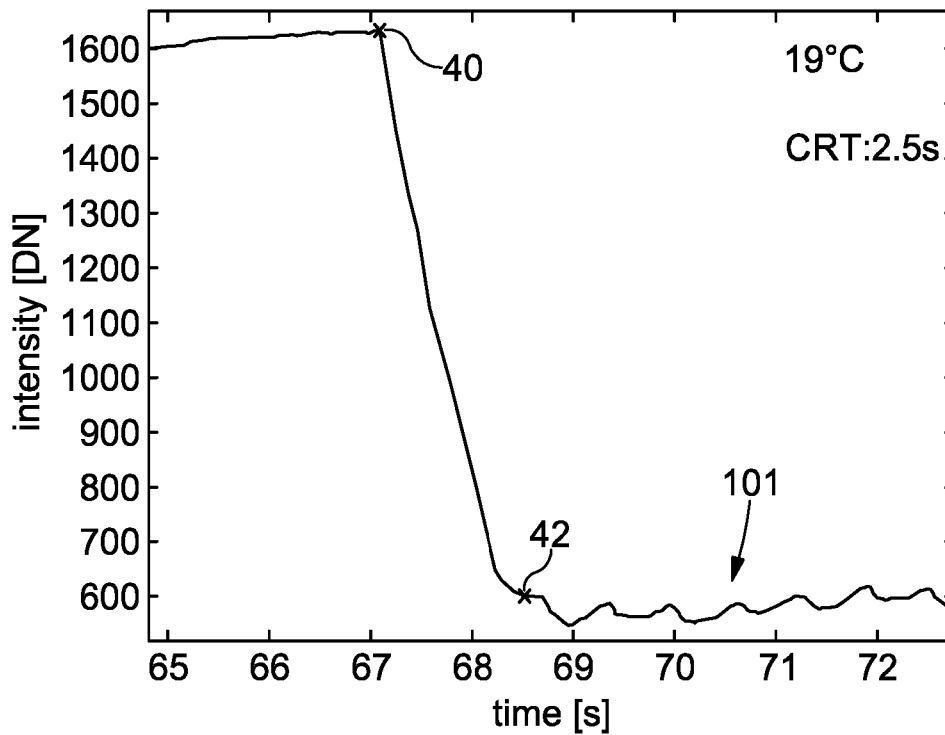


Figure 12

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/GB2015/051071

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61B5/00      A61B5/026      G01G19/50 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) A61B G01G		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/053920 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; PHILIPS INTERNAT PROPERTY AND; UZ) 30 April 2009 (2009-04-30)	1-3,5, 13-15, 19,21, 25,26
Y	page 11, lines 1-34 page 13, line 26 - page 14, line 17 figures 5-7	4,6-12, 16-18, 20,22-24
X	----- A.N. NICOLAIDES: "Investigation of Chronic Venous Insufficiency - A Consensus Statement", CIRCULATION, vol. 102, 19 July 2000 (2000-07-19), pages e126-e163, XP002740576, DOI: 10.1161/01.CIR.102.20.e126 PPG, Light Reflection Rheography, and Quantitative Digital PPG; page e133 - page e135 ----- -/--	1,27-31
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search <p align="center">8 June 2015</p>		Date of mailing of the international search report <p align="center">16/07/2015</p>
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer <p align="center">Bataille, Frédéric</p>

INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2015/051071

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/018241 A1 (BEZZERIDES VASSILIOS [US] ET AL) 17 January 2013 (2013-01-17) paragraphs [0037], [0038], [0045] - [0059] -----	4, 16-18
Y	US 2010/249557 A1 (BESKO DAVID [US] ET AL) 30 September 2010 (2010-09-30) paragraphs [0019] - [0024], [0038] -----	6-12, 20, 22-24
A	US 5 396 896 A (TUMEY DAVID M [US] ET AL) 14 March 1995 (1995-03-14) the whole document -----	1-31

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2015/051071
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Patent document cited in search report	Publication date	Publication date	Patent family member(s)	Publication date
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			WO 2011078882 A1	30-06-2011
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专利名称(译)	毛细管填充测量		
公开(公告)号	<a href="#">EP3128900A1</a>	公开(公告)日	2017-02-15
申请号	EP2015717600	申请日	2015-04-08
[标]申请(专利权)人(译)	诺丁汉大学		
申请(专利权)人(译)	英国诺丁汉大学		
当前申请(专利权)人(译)	英国诺丁汉大学		
[标]发明人	KORPOSH SERGIY MORGAN STEPHEN HAYES GILL BARRIE		
发明人	KORPOSH, SERGIY MORGAN, STEPHEN HAYES-GILL, BARRIE		
IPC分类号	A61B5/00 A61B5/026 G01G19/50		
CPC分类号	A61B5/02028 A61B5/0022 A61B5/01 A61B5/02055 A61B5/0261 A61B5/1036 A61B5/441 A61B5/6807 A61B5/6829 A61B5/6892 A61B2562/0233 A61B2562/164 A61B2562/228 G01G19/50		
代理机构(译)	LAWRENCE , JOHN		
优先权	2014006343 2014-04-08 GB		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

一种毛细管再填充测量装置(1)，包括：支撑元件(14)，被配置为通过他们的脚接收使用者的重量；光源(22)，用于照射足部的区域，其将重量施加到支撑元件上(14)，光检测器(24)，其布置成接收来自脚的照射区域(36)的光并基于所接收的光产生输出；以及处理器(26)，其被配置为从输出的输出确定毛细管再填充率。当用户调节由支撑元件(14)接收的重量时，光检测器(24)。