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(54) **FOOT ORTHOTIC**

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(76) Inventors: **Jeffrey M. Alaimo**, Lutz, FL (US);
Gregory A. Alaimo, Tampa, FL (US)

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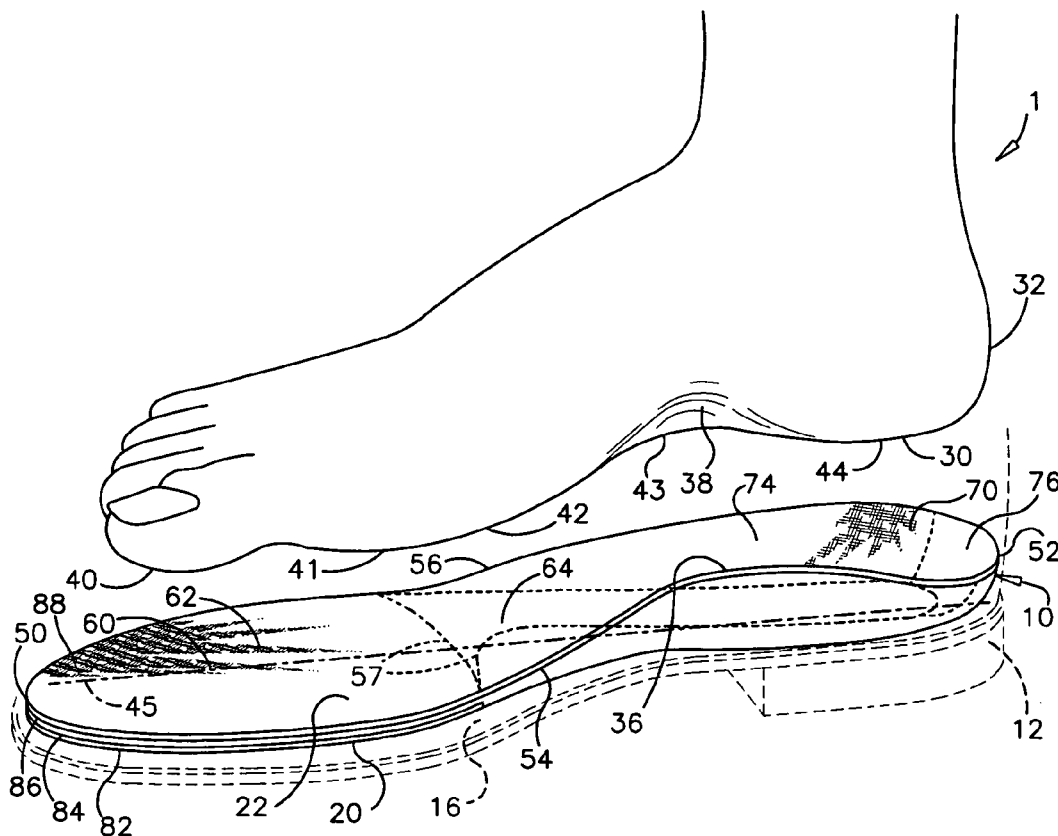
Correspondence Address:
Mitchell Rose, Ph.D.
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, OH 44114 (US)

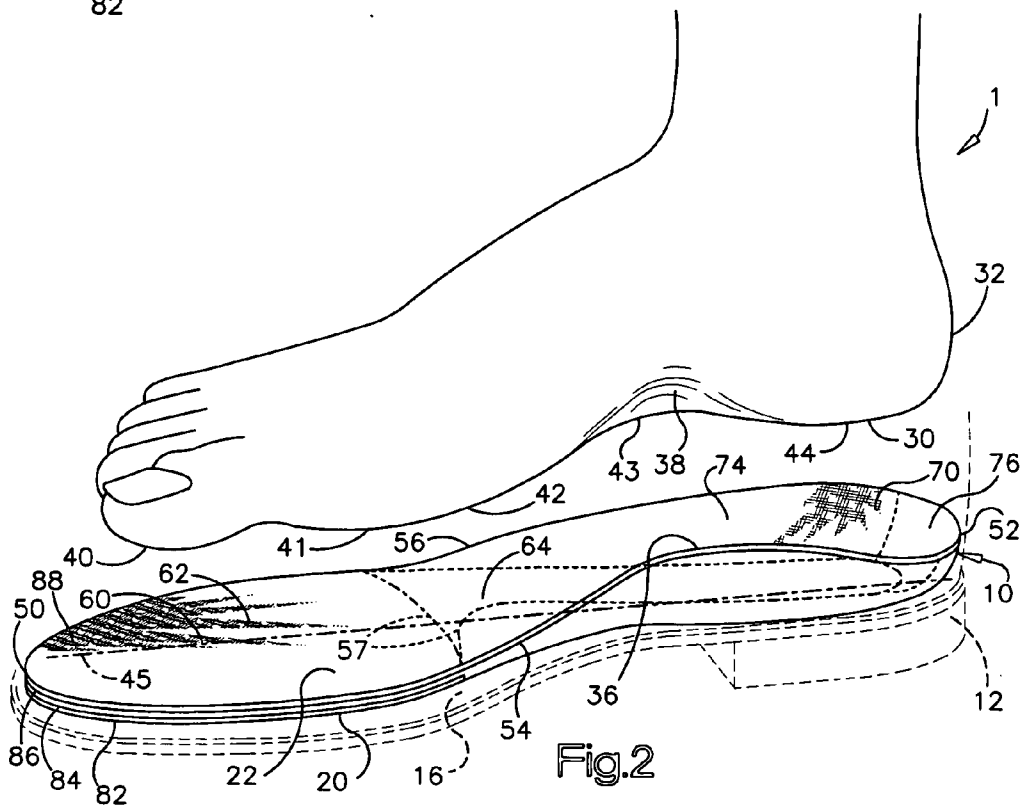
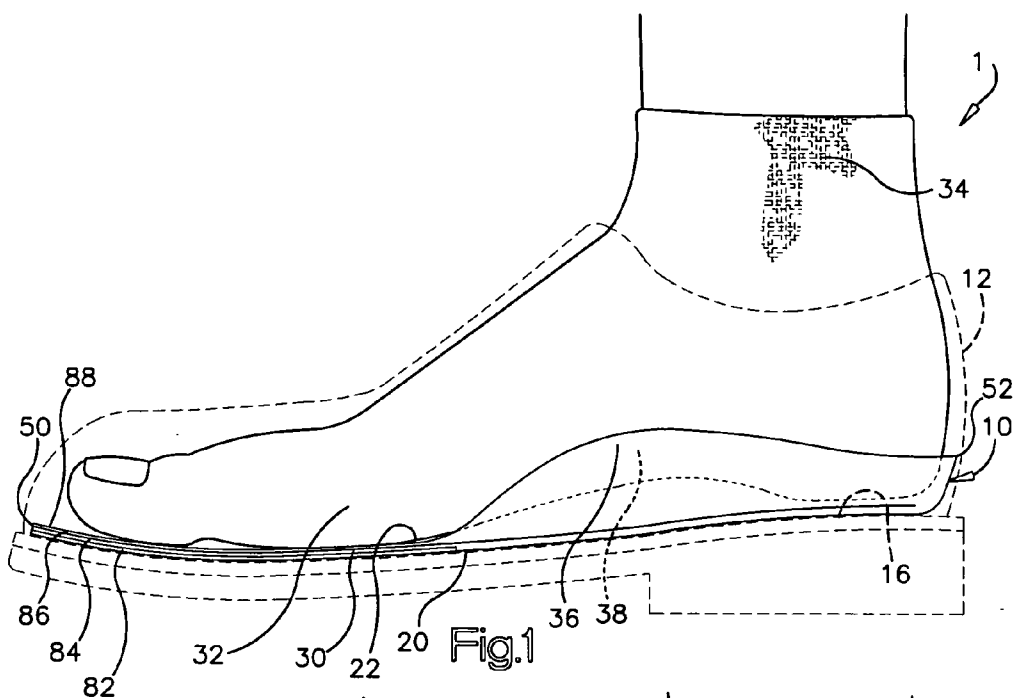
(57) **ABSTRACT**

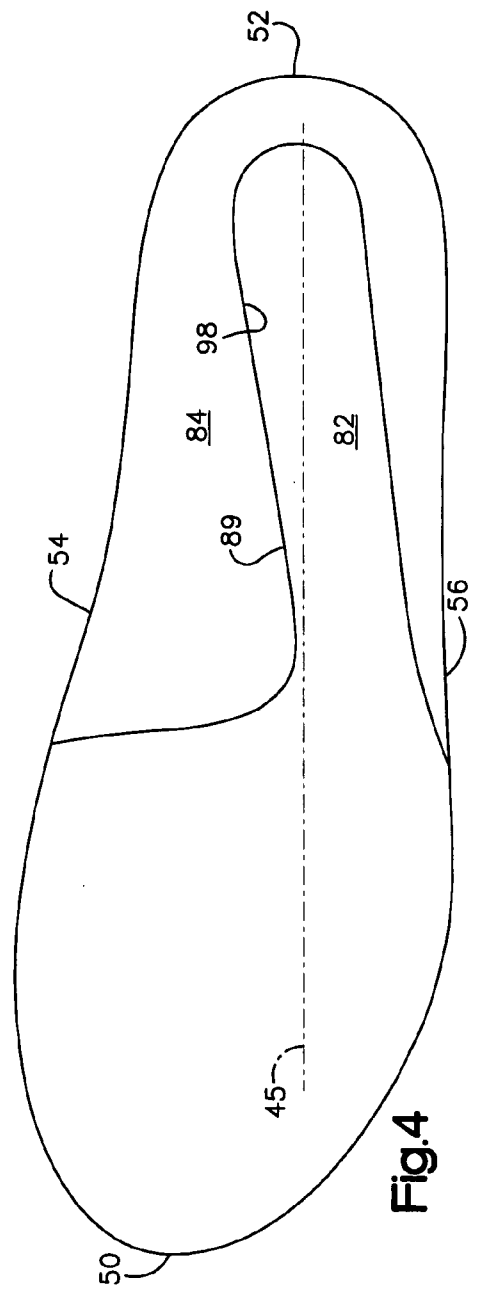
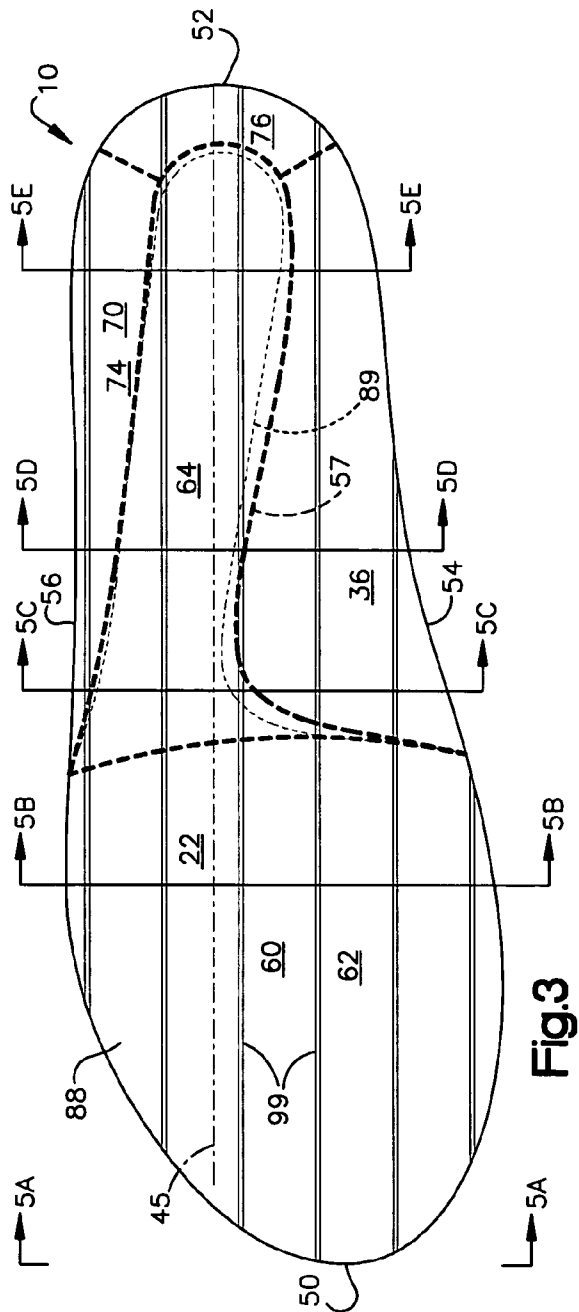
A foot orthotic is configured to be removably installed in a shoe and includes an upper layer, a middle layer and a lower layer adhered together. The upper layer is formed of a viscoelastic material. The middle layer is formed of a thermoplastic material. The lower layer is formed of a thermoset material.

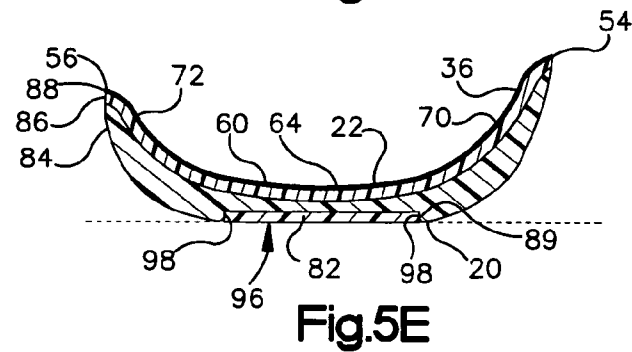
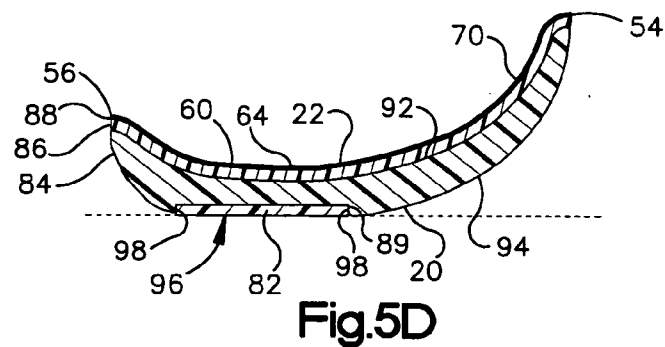
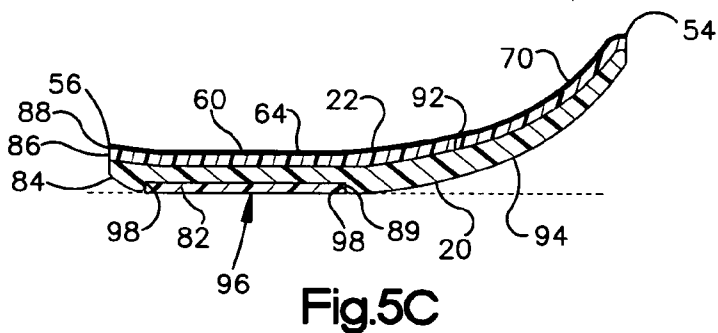
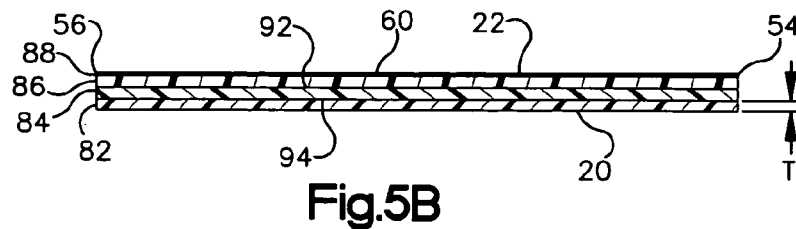
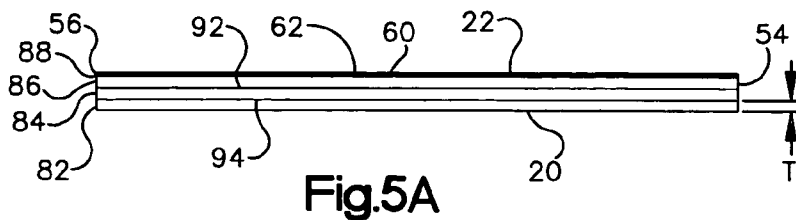
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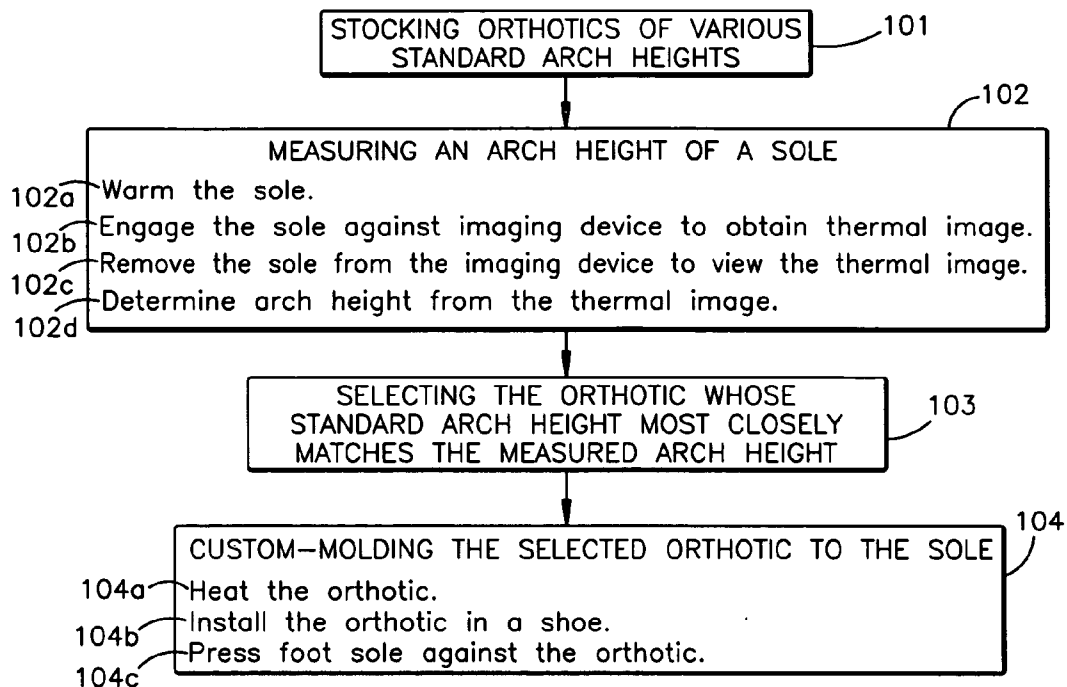


Fig.6

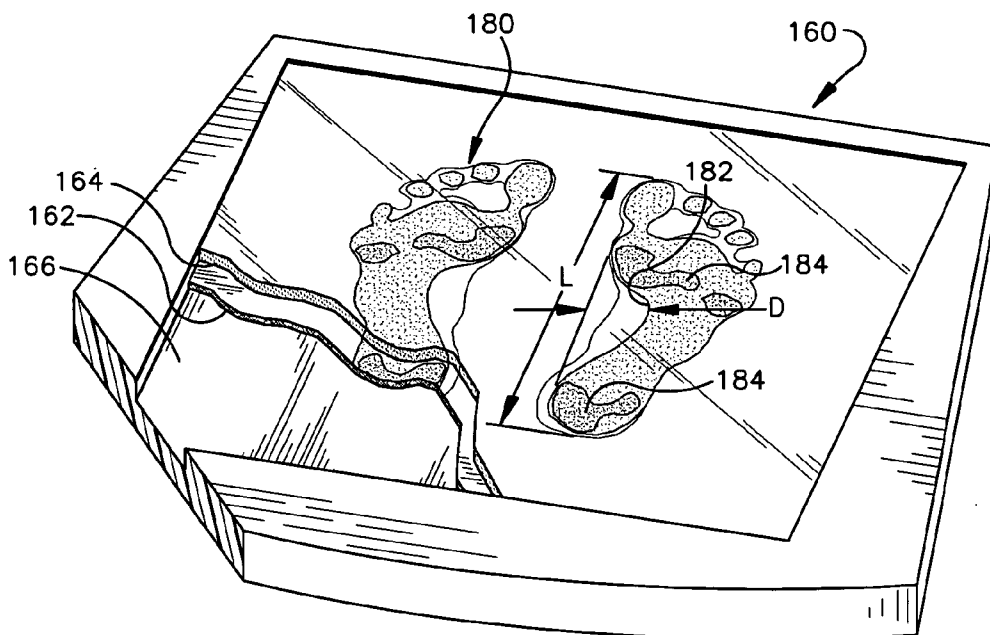


Fig.8

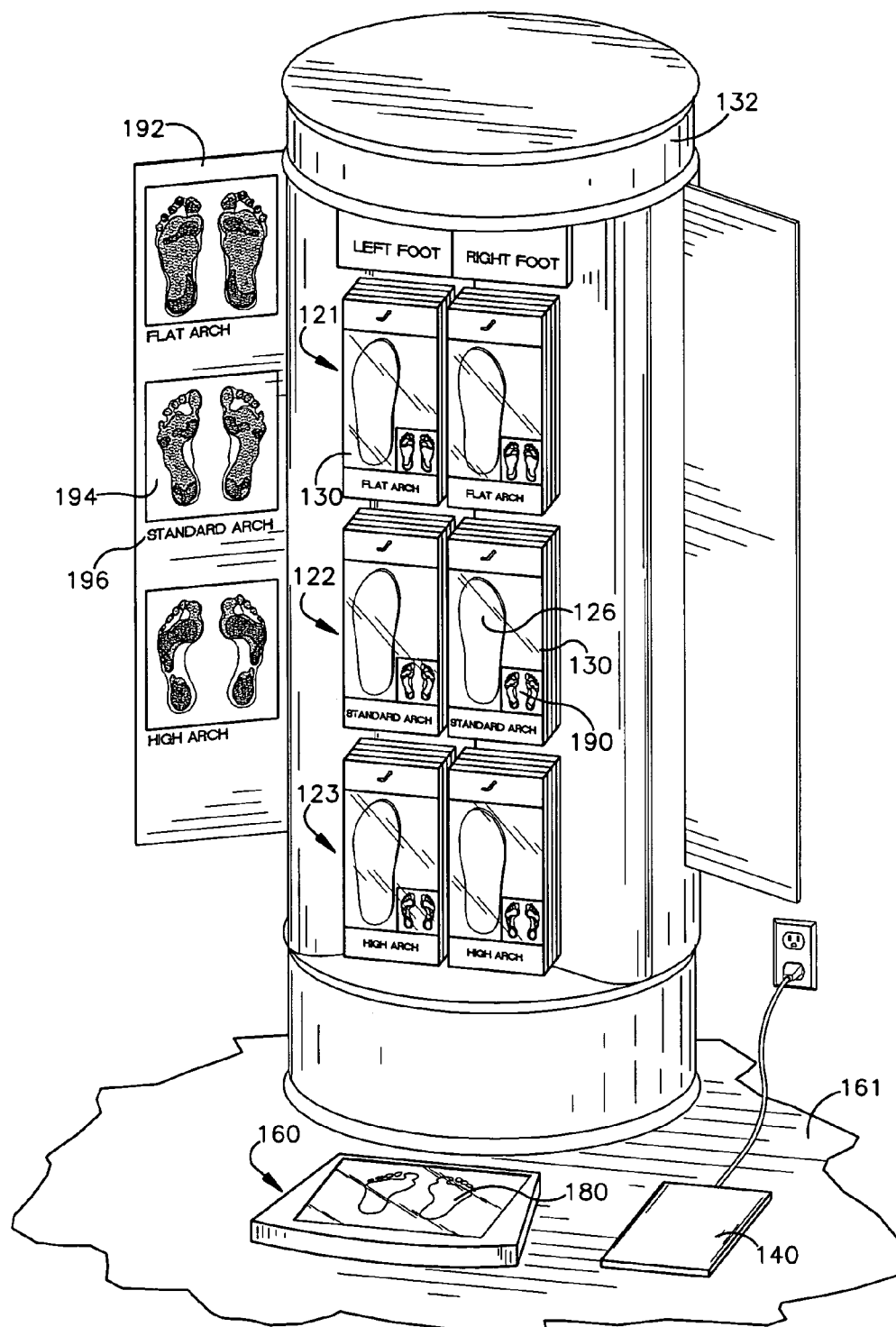


Fig.7

FOOT ORTHOTIC

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a division of U.S. application Ser. No. 10/648,065, filed Aug. 26, 2003, hereby incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to foot orthotics.

BACKGROUND

[0003] A foot orthotic is configured to be removably installed in a shoe. Within the shoe, the orthotic lies between an insole of the shoe and a sole of a foot to cushion the foot. An arch of the orthotic supports the arch of the foot.

SUMMARY

[0004] A foot orthotic is configured to be removably installed in a shoe and comprises an upper layer, a middle layer and a lower layer adhered together. The upper layer is formed of a viscoelastic material. The middle layer is formed of a thermoplastic material. The lower layer is formed of a thermoset material.

[0005] Another foot orthotic is configured to be removably installed in a shoe and comprises an upper layer, a middle layer and a lower layer adhered together. The upper layer is formed of a viscoelastic material. The middle layer is formed of a thermoplastic material with a softening temperature of about 55-80° C., whereby the orthotic can be pressed by a foot while the middle layer is in a heat-softened state during a custom-molding process but will not heat-soften during normal use. The lower layer is formed of a material that will not heat-soften below about 90° C., whereby the lower layer will not heat-soften during the custom-molding process.

[0006] Preferably, the middle layer is stiffer than the upper and lower layers. The orthotic further comprises a fabric layer, overlying the upper layer, that contains elemental silver configured to kill bacteria. A thermal tag that changes color at a predetermined temperature is adhered to a surface of the orthotic.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a side view of a foot orthotic in accordance with the present invention, shown installed in a shoe and lying between an insole of the shoe and a sole of a foot;

[0008] FIG. 2 is a perspective view of the orthotic, the shoe and the foot, showing the foot spaced above the orthotic;

[0009] FIG. 3 is a top view of the orthotic;

[0010] FIG. 4 is a bottom view of the orthotic;

[0011] FIGS. 5A-5E are sectional views taken, respectively, at lines 5A-5E of FIG. 3;

[0012] FIG. 6 is a flow chart of steps in a method for use with the orthotic;

[0013] FIG. 7 is a perspective view of an apparatus for use in the method of FIG. 6; and

[0014] FIG. 8 is a perspective view of a part shown in FIG. 7.

DESCRIPTION

[0015] The apparatus 1 shown in FIG. 1 has parts which, as described below, are examples of the elements recited in the claims.

[0016] The apparatus 1 includes a foot orthotic 10. The orthotic 10 can be removably installed in a shoe 12, in an installed position in which it lies flat over an insole 16 of the shoe 12. A bottom surface 20 of the orthotic 10 has a shape corresponding to that of the insole 16. A top surface 22 of the orthotic 10 has a shape corresponding to that of a sole 30 of a foot 32, shown covered by a sock 34. The orthotic 10 has elastic and viscoelastic properties to cushion the foot 32. The orthotic 10 also has a medial arch 36 to support a medial arch 38 of the foot 32. The orthotic 10 can be plastically deformed when heated to a heat-softened state. Accordingly, the orthotic 10 can be custom-molded to the shape of the foot sole 30 by a process entailing pressing the foot sole 30 against the orthotic 10 while the orthotic 10 is in the installed position while in the heat-softened state.

[0017] The orthotic 10 is described below with reference to sections of the sole 30 of the foot 32. As shown in FIG. 2, these sections comprise toes 40, metatarsal heads 41, a ball 42, a midfoot 43 and rearfoot 44 (heel). The foot arch 40 is part of the midfoot 43.

[0018] The orthotic 10 is elongated along an axis 45, and is bounded axially by front and rear edges 50 and 52. It is bounded transversely by medial (inner) and lateral (outer) side edges 54 and 56.

[0019] In FIGS. 2 and 3, sections of the orthotic 10 are delineated by dashed lines 57. The orthotic 10 has a flat section 60 comprising a flat broad front portion 62 and a flat elongated rear portion 64 that projects rearward from the broad front portion 62. The broad front section 62 supports the toes 40, the metatarsal heads 41 and the ball 42 of the foot 32. The elongated rear portion 64 supports the midfoot 43 and the rearfoot 44.

[0020] Partially surrounding the narrow rear portion 64 is an upturned section 70. The upturned section 70 comprises the axially-extending medial (inner) arch 36, an axially-extending lateral (outer) arch 74, and an arcuate rear arch 76. The flat narrow rear portion 64 and the surrounding upturned section 70 together cup the midfoot 43 and rearfoot 44.

[0021] As shown in FIGS. 4 and 5A-5E, the orthotic 10 is formed as a stack of layers. The layers comprise a lower layer 82, a middle layer 84, an upper layer 86, a top covering 88 that are adhered together. Each layer 82, 84, 86 and 88 has a particular physical property that contributes to the overall characteristics of the orthotic 10.

[0022] The lower layer 82 comprises a generally flat piece of material. The material is flexible in that it can bend. It is microcellular in that it has small pores. It is compressible in that it exhibits significant volume change under pressure, due to the pores. It is elastic in that it quickly recovers upon release from applied pressure or torsion. The material can be a thermoset material in that it will not heat-soften at any temperature. Alternatively, the material can be a thermoplastic material that will not heat-soften at any temperature applied

during the custom-molding process. Accordingly, the material of the lower layer **82** is a material, such as a thermoset, that will not heat-soften below about 90° C. (194° F.) and more preferably not heat soften below about 100° C. (212° F.). This helps ensure that the thickness of the lower layer **82** will not vary during the custom-molding process. The material is preferably a polyurethane.

[0023] A peripheral edge **89** of the lower layer **82** is denoted by a thin dashed line in the top view of **FIG. 3** and by a solid line in the bottom view of **FIG. 4**. The shape of the lower layer **82** approximately corresponds to the shape of the flat section **60**. The lower layer **82** extends across approximately the entire flat section **60** and is absent across approximately the entire turned-up section **70**. The lower layer **82** has an approximately uniform thickness **T** (**FIG. 5A**) over its entire area bounded by the peripheral edge **89**. During the custom-molding process, the lower layer **82** insulates the shoe insole **38** from the high temperature of the middle layer **84**, and insulates a section of the middle layer **84** overlying the lower layer **82** from cooling off quickly, and, further, provides a section of the orthotic **10** that is sure not to thin out.

[0024] The middle layer **84** is best shown in **FIGS. 4** and **5A-5E**. It comprises a material that is microcellular and compressible. This material is flexible and elastic, yet stiffer than the materials of the other layers **82** and **84**. The material of the middle layer **84** is a thermoplastic having a softening temperature. Above the softening temperature, the material is in a heat softened state in which it can plastically deform for custom-molding the orthotic **10** to the foot sole **30**.

[0025] The softening temperature is higher than the highest temperature the orthotic **10** is likely to be exposed to during use, when it is worn in the shoe **12**. This prevents plastic deformation of the orthotic **10** during use. Accordingly, the softening temperature is preferably at least about 55° C. (131° F.) and more preferably at least about 60° C. (140° F.). However, the softening temperature must be lower than the temperature applied to the middle layer **84** in the custom-molding process. Accordingly, the softening temperature of the middle layer **84** is preferably up to about 75° C. (167° F.), and more preferably up to about 70° C. (158° F.). The material is preferably an ethylene vinyl acetate (EVA).

[0026] The middle layer **84** extends over the entire area of the orthotic **10**, bounded by the front, rear, medial and lateral edges **50**, **52**, **54** and **56**. The middle layer **84** is generally flat in the flat section **60** of the orthotic **10** and upturned in the upturned section **70** of the orthotic **10**. Most of the stiffness of the orthotic **10**, especially in the upturned section **70**, is provided by the middle layer **84**.

[0027] The middle layer **84** has top and bottom surfaces **92** and **94** shown in **FIGS. 5A-5E**. The top surface **92** is completely covered by the upper layer **86**. The bottom surface **94** is covered by the lower layer **82** in the flat section **60** of the orthotic **10** and is exposed in the upturned section **70**. The bottom surface **94** of the middle layer **84** defines a recess **96** with sides **98** that closely receive the lower layer **82**.

[0028] The upper layer **86** overlies the entire middle layer **84**. The upper layer **86** comprises a material that is microcellular, compressible and flexible. This material is vis-

coelastic in that it exhibits slow recovery upon release from applied pressure. During use, this cushions the foot **32** with a soothing viscoelastic material separated from the foot **32** only by the top covering **88**. During the custom-molding process, this layer insulates the foot **32** from the temperature of the middle layer **84** and insulates the middle layer **84** from cooling off too quickly. The material is a thermoplastic, with a softening temperature conforming to the ranges stated above for the middle layer **84**. Therefore, the material of the upper layer **86** will plastically deform during the custom-molding process but not during use. The softening temperatures of the middle and upper layers **84** and **86** are preferably approximately equal. The material of the upper layer **86** is preferably an ethylene vinyl acetate (EVA).

[0029] Alternatively, the material can either be thermoset, or at least not heat soften at temperatures applied during the custom-molding process. This prevents the thickness of the upper layer **86** from varying during the custom-molding process.

[0030] The top covering **88** is a fabric overlying the entire upper layer **86**. The fabric includes elemental silver. Preferably, the silver is present in the form of silver-containing fibers that are woven into the fabric. The fiber can be a silver-coated nylon fiber, as exemplified by X-Static® fiber sold by Noble Fiber Technologies of Clarks Summit, Pa. As shown in **FIG. 3**, the silver fibers can be woven into the fabric to form transversely-spaced parallel stripes **99** of silver extending axially along the length of the orthotic **10**. The silver-coated fibers can be configured, in terms of amount and location within the fabric, to kill bacteria and fungus, to absorb odor, to conduct heat away from the foot **32** (**FIG. 2**) to the front and rear edges **50** and **52** of the orthotic **10**, to reflect heat emitted by the foot **32** back toward the foot **32** and/or to dissipate static charge.

[0031] The top covering **88** is preferably configured, in terms of fiber type and weave, to thermally insulate the foot **32** from the heat of the orthotic **10** during the custom-molding process. This enables the custom-molding temperature, and thus also the softening temperature of the middle layer **84**, to be higher than if the top covering **88** were absent. The top layer **88** further provides a surface that is smoother than the upper layer **86**, over which the sock-covered foot can slide easily.

[0032] The orthotic **10** described above is well suited for use with a method presented in **FIG. 6** for providing an orthotic. This method comprises the major steps of stocking **101** orthotics of various standard arch heights, measuring **102** an arch height of a sole, selecting **103** an orthotic whose standard arch height most closely matches the measured arch height, and custom-molding **104** the selected orthotic to the sole. These steps are illustrated by the following example, which takes place in a shoe store.

[0033] The stocking step **101** is explained as follows with reference to **FIG. 7**. The store stocks three sets **121**, **122** and **123** of orthotics **126**. The orthotics **126** are packaged in boxes **130** hanging on a merchandise rack **132**. Each set **121**, **122** and **123** comprises orthotics **126** having a standard arch height that is unique for that set. The three standard arch heights for the three sets **121**, **122** and **123** in this example are flat, standard and high, respectively, with standard corresponding to a median foot arch height. The middle layers **84** (**FIG. 5A**) of the orthotics **126** can be color-coded to

indicate arch height. For example, the middle layers **84** can be blue, green and yellow, respectively, for orthotics **126** of low arch **121**, standard arch **122** and high arch **123**.

[0034] Both the number of sets and the standard arch height designated for each set are predetermined based on various competing considerations. These considerations include a preference to minimize the number of sets to minimize stocking expenses. There is also a preference to minimize the differences between successive standard arch heights to minimize the extent an orthotic **126** will need to be reshaped in the custom-molding process. There is also a preference that the full range of standard arch heights be sufficiently broad to satisfy the full range of customers' arches likely to be encountered.

[0035] In the measuring step **102** (FIG. 6), a customer enters the store to buy orthotics for his feet. The customer's arch height is measured without the customer needing to try on an orthotic. This is done by the customer first removing his shoes and socks from his feet. In a warming sub-step **102a**, he warms the soles of the feet by standing on a warming pad **140**, shown in FIG. 7, for a short time, such as 30 seconds.

[0036] Then, he engages (**102b** in FIG. 6) the soles of his feet against an imaging device **160** that exhibits a change in color with a change in temperature. This is done by simply standing on the imaging device **160** for a short time, such as 15 seconds. The device **160** produces a thermal image of the foot sole, in the form of a thermal footprint, based on the difference in temperature between the sole and the device. Then, the customer removes (**102c** in FIG. 6) his feet from the device to view the thermal image.

[0037] The imaging device **160** has the configuration of a flat plate lying on the ground **161**. It has no moving parts, no electrical parts and no power cord. It is thus unobtrusive, yet easily accessible by the customer. In this example, it is positioned adjacent to, in front of, the merchandise rack **132**. A customer's curiosity about the imaging device **160** will draw him to the merchandise rack **132**, and vice versa.

[0038] The imaging device **160** is shown in more detail in FIG. 8. It includes a liquid-crystal-based thermal paper **162**, which is a thermally sensitive material that exhibits a change in color with a change in temperature. The color change can be a change in shade or intensity of a color, or a change to a different color. The paper **162** is sandwiched between a transparent plastic upper plate **164** to protect the thermal paper from abrasion and a rigid plastic lower plate **166** to prevent the thermal paper **162** from bending. Engagement of the foot sole against the upper plate **164** causes the thermal paper **162** to change color at locations at which the upper plate **164** is close to or contacting the sole. At each location on the thermal paper **162**, the color change is more pronounced with closer proximity to the sole and with greater pressure against the sole.

[0039] An example **180** of the thermal image produced by the substrate is shown in FIG. 8. The image **180** exhibits a typical inward bow **182** in the arch area. The depth *D* of the inward bow **182** relative to the length *L* of the footprint **180** is indicative of the customer's arch type. The image **180** can be used to determine other characteristics of the sole than arch height. For example, pressure points **184**, which are locations on the sole that press more strongly against the

shoe insole, exhibit more pronounced color change. Conversely, restricted blood flow locations of the sole exhibit less pronounced color change. Any information derived from the thermal image **180** relates to the condition of the sole while bearing down on the ground with full body weight. This is in contrast to the sole being raised off the ground for a visual examination by a physician. The footprint **180** gradually fades and the device **160** used again.

[0040] In a determining sub-step **102d**, the customer or a store clerk determines the arch height from the thermal image **180**, based on the depth *D* of the inward bow **182**. This determination **102d** can be done objectively, such as by measuring the depth *D* with a ruler, or subjectively without taking an actual length measurement. The determination sub-step **102d** can be simply a rough estimate, such as by choosing the most closely matching standard arch height from a choice of the three possibilities (flat, standard and high).

[0041] To facilitate the determination sub-step **102d**, each box **130** in FIG. 7 is imprinted with a reference thermal image **190**, or reference footprint, that is indicative of the arch type of the orthotic **126** in the box **130**. The customer subjectively compares the thermal image **180** of his own sole with those **190** on the boxes **130**, and selects the box **130** providing the closest match. Instead of, or in addition to, the reference images **190** being printed on the boxes **130**, reference images **194** can be printed on another medium, such as a poster **192**, with each reference image **194** labeled with its corresponding designation **196**, such as "flat" or "high" or a numeric measure of arch height.

[0042] As described above, the customer removes his socks before stepping on the warming pad **140** and the imaging device **160**. The socks are removed so that they do not insulate the feet from the warming pad **140** or the imaging device **160**. However, to avoid being barefoot, the customer can place disposable plastic bags over his feet. The wall of the bag should be thin to minimize the insulating effect.

[0043] As described above, the customer warms his feet on a warming pad **140** before stepping on the imaging device **160**. This is to ensure that the feet are sufficiently warmer than the thermal paper **162** (FIG. 8) to yield a clear thermal image **180**. But this pre-warming may not be needed. The need for pre-warming the feet depends on the initial warmth of the feet and a transition-temperature of the thermal paper **162**.

[0044] As an alternative to the customer's feet being pre-warmed, the thermal paper **162** (FIG. 8) can be pre-warmed to a temperature that is warmer than the feet. Then, when the customer stands on the imaging device **160**, different locations on the thermal paper **162** are cooled to different extents, yielding corresponding color changes. The extent of the cooling at each location is related to proximity and pressure of that location with the foot sole. This yields a thermal image that can be used to determine the closest standard arch height.

[0045] In the selecting step **103** (FIG. 6), the customer or a store clerk selects an orthotic **126** from the set **121**, **122** and **123**, shown in FIG. 7, whose standard arch height most closely matches the measured arch height. This can mean simply selecting an orthotic **126** from the set **121**, **122** and

123 that is indicated in the measuring step **102**. The selected orthotic **10** is installed in the shoe **12** in the installed position shown in **FIG. 1**. The customer inserts his foot **32** in the shoe **12** to determine whether the fit to his foot **32** is satisfactory. If the fit is unsatisfactory, the fit can be improved by custom-molding the orthotic **10** to the customer's foot in accordance with the following custom-molding step **104** (**FIG. 6**).

[**0046**] The custom-molding step **104** corresponds to the following process. First, the orthotic **10** is heated (**104a** in **FIG. 6**) to raise the middle layer **84** to an initial temperature that is above the softening temperature. The initial temperature is sufficiently high such that the middle layer **84** will remain above the softening temperature at least until the end of the custom-molding process. In this example, the orthotic **10** is heated in an oven set at a specified temperature, such as 93° C. (200° F.), for a specified time, such as two minutes. Alternatively, the orthotic **10** can be heated at a specified temperature until a certain portion of the orthotic **10** reaches a specified temperature. This can be done with a thermal tag that changes color at a specified temperature, such as 71° C. (160° F.). The tag is adhered to the bottom or top surface **20** or **22** of the orthotic **10**. Then, the orthotic **10** is heated in the oven until the tag changes color.

[**0047**] Next, the orthotic **10** is installed (**104b** in **FIG. 6**) in the shoe **32** in the installed position shown in **FIG. 1**. The customer inserts his foot **32**, covered by a sock **34**, into the shoe **12**. He stands upright, for typically 0.5-1 minute, and/or walks around, for typically 2-3 minutes. Doing so presses (**104c** in **FIG. 6**) the foot sole **30** against the orthotic **10** while the middle layer **84** is still in the heat-softened state and can plastically deform. This is done with sufficient pressure and for sufficient time for the orthotic **10** to conform to the shape of the foot sole **30** from above and the shape of the insole **16** from below. This conformity implies a correspondence in shape without implying an actual match in shape. The conformity can entail bending of the middle layer **84**. It can further entail areas of the middle layer **84** that are under greater pressure from the sole **30** being thinned out, with the resulting displaced material moving to areas that are subjected to less pressure. The custom-molding process is thus complete.

[**0048**] During the pressing sub-step **104c**, the temperature of the middle layer **84** can be higher than the highest temperature the foot can tolerate, by a certain value. This value is related to the insulating properties of the sock **34**, the top covering **88** and the upper layer **86**. Based on these considerations, the temperature of the middle layer **84** during the pressing sub-step **104c** should not exceed about 80° C. (176° F.).

[**0049**] As indicated above, during the pressing sub-step **104c**, the sole is covered and insulated by the customer's own sock. However, the sole can instead be covered by a material with a thickness similar to that of the sock, but with a much higher insulating value than the sock. That would enable the temperature of the middle layer **84** during the pressing sub-step **104c** to be correspondingly higher, such as up to 85° C. (185° F.). The softening temperature of the middle layer **84** could then be up to about 80° C. (176° F.). Such an insulating material could be a Styrofoam sheet fashioned into the shape of a sock.

[**0050**] The above explanation of the custom molding process **104** includes considerations relating to the molding

and softening temperatures of the middle layer **84**. These considerations apply also to the molding and softening temperatures of the upper layer **86** if it, too, has a softening temperature and is configured to plastically deform during the custom-molding process.

[**0051**] As mentioned above, the preferred imaging device **160** (**FIG. 8**) includes a thermally sensitive material **162** that exhibits a change in color with a change in temperature to yield a thermal footprint **180**. Alternatively, the material **162** can be a pressure sensitive material, possibly liquid crystal, that exhibits a change in color with a change in pressure. The resulting footprint **180** would not indicate temperature-related foot characteristics, such as restricted blood flow locations. Also, the customer would not have to remove his socks, because such an alternative imaging device is not based on temperature sensing. The image can fade with time, and the device used again.

[**0052**] This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to make and use the invention. The patentable scope of the invention is defined by the claims, and may include other examples that occur to those skilled in the art. Such other examples are intended to be within the scope of the claims if they have elements that do not differ from the literal language of the claims, or if they include equivalent structural elements with insubstantial differences from the literal language of the claims.

1. A foot orthotic comprising:

an upper layer formed of a viscoelastic material;

a middle layer formed of a thermoplastic material; and

a lower layer formed of a thermoset material;

the layers being adhered together, and the orthotic being configured to be removably installed in a shoe.

2. The orthotic of claim 1 wherein the thermoplastic material has a softening temperature of about 55-80° C., whereby the orthotic can be pressed by a foot while the middle layer is in a heat-softened state during a custom-molding process but will not heat-soften during normal use.

3. The orthotic of claim 1 further comprising a thermal tag that changes color at a predetermined temperature, adhered to a surface of the orthotic.

4. The orthotic of claim 1 further comprising a flat section and an upturned section, wherein an outline of the flat section has approximately the same shape as a peripheral edge of the lower layer.

5. The orthotic of claim 1 further comprising a flat section and an upturned section, wherein an outline of the flat section closely follows a peripheral edge of the lower layer.

6. The orthotic of claim 1 further comprising a fabric layer, overlying the upper layer, that contains elemental silver configured to kill bacteria.

7. A foot orthotic comprising:

an upper layer formed of a viscoelastic material;

a middle layer formed of a thermoplastic material with a softening temperature of about 55-80° C., whereby the orthotic can be pressed by a foot while the middle layer is in a heat-softened state during a custom-molding process but will not heat-soften during normal use; and

a lower layer formed of a material that will not heat-soften below about 90° C., whereby the lower layer will not heat-soften during the custom-molding process;

the layers being adhered together, and the orthotic being configured to be removably installed in a shoe.

8. The orthotic of claim 7 wherein the middle layer is stiffer than the upper and lower layers.

9. The orthotic of claim 7 further comprising a fabric layer, overlying the upper layer, that contains elemental silver configured to kill bacteria.

10. The orthotic of claim 7 further comprising a flat section and an upturned section, wherein an outline of the flat section has approximately the same shape as a peripheral edge of the lower layer.

11. The orthotic of claim 7 further comprising a flat section and an upturned section, wherein an outline of the flat section closely follows a peripheral edge of the lower layer.

12. The orthotic of claim 7 further comprising a thermal tag that changes color at a predetermined temperature, adhered to a surface of the orthotic.

* * * * *