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(54) Title: TEMPERATURE REGULATING FOOTWEAR

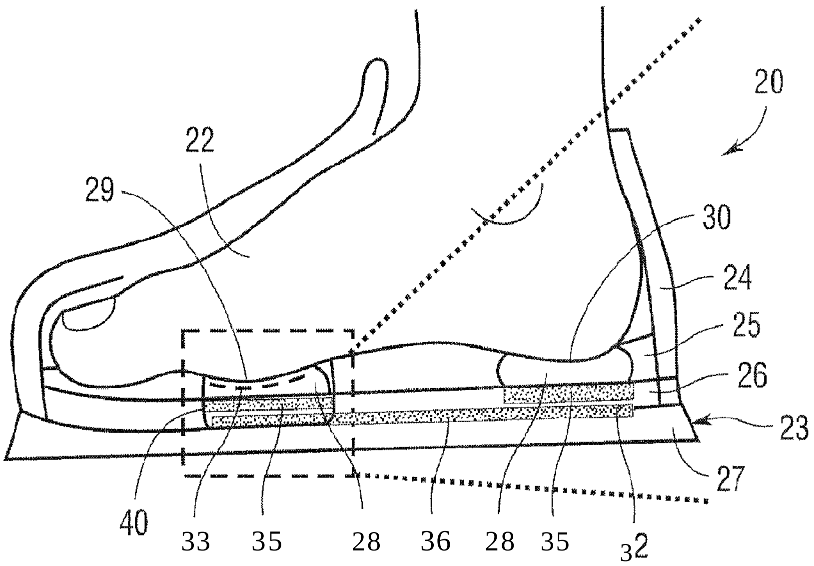

Fig.2

(57) Abstract: A footwear product with an integrated active temperature control system comprising: an upper; a sole comprising an insole comprising one or more thermo-conductive inserts or plugs; a midsole disposed between the insole and an outsole; wherein the midsole comprises one or more cooling elements selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element; and one or more heat sinks disposed in the midsole, outsole or between the midsole and outsole.

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Temperature Regulating Footwear

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of the filing date of U.S. provisional patent application Ser. No. 62/238,057, filed on October 6, 2015, the entirety of which is incorporated herein by reference for all purposes.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with government support under grant #DGL 1144584. The government has certain rights in the invention.

TECHNICAL FIELD

[0003] The present disclosure generally relates to apparatus for regulating temperature with footwear and kits for retrofitting footwear for the same purpose.

Background of the Disclosure

Description of the need and target population

[0004] An estimated 1.6 million people in the United States live with limb loss. By 2050 that number may be as high as 3.63 million due to growth in the aging population and an increase in the number of people with dysvascular diseases such as diabetes. This prevalence reflects the significance of amputations and serves as a compelling basis for future research. Prior to amputation, individuals with diabetes are at a high risk for soft tissue complications. According to the Centers for Disease Control and Prevention, diabetes mellitus affects 25.8 million people, which is about 8.3% of the U.S. population. People with diabetes have a 25% lifetime risk of developing diabetic foot ulcers (DFU), and once an ulcer is formed, 84% of the cases will lead to lower extremity amputation (LEA). A study conducted at the Karolinska University Hospital in Sweden reported that 88% of non-traumatic lower extremity amputations were performed due to foot ulceration, confirming the high risk associated with this condition.

[0005] Development of DFU and subsequent LEA affects a person's health and function as well as quality of life, including reduction or loss of mobility, independence, inability to work, anxiety of possible development of new ulcers, depression and social isolation. In addition, treating DFU is costly; diabetic foot ulcers were estimated to cost the Medicare system 1.5 billion dollars annually. These costs include treatment of non-infected and infected ulcers, ulcers that progress to amputation, surgery and post amputation treatment.

Need for innovation in therapeutic footwear

[0006] Diabetic foot ulcers are multifactorial conditions, and the major underlying causes are peripheral neuropathy and peripheral vascular ischemia. Peripheral neuropathy causes foot deformities, lack of sensation, and dry skin that is susceptible to tearing. Changes in microvascular function include impaired vasodilator response, decreased blood flow, and endothelial dysfunction leading to tissue ischemia of the lower extremities. These alterations lead to repetitive high pressure points at the bony prominences, occlusive arterial disease and eventually ischemia in the lower extremity. Current insoles prescribed to patients at risk focus only on reducing the pressure concentrated at the bony prominences, however pressure is inevitable with daily activities (e.g., walking, standing). There is a need to develop therapeutic footwear insoles that will optimize tissue viability during ambulation and other daily activities.

[0007] Thermal control of the skin has been proven to maintain tissue viability during ischemia in animals and humans; this is primarily because lowering temperature reduces the ischemic tissue metabolism by 6-13% per °C. Two iconic animal studies investigated the effect of temperature on ulcer development. Kokate et al., performed histological examination of the skin in swine after the skin was subjected to lOOmmHg of pressure at different temperatures ranging from 25 to 45°C for five hours. They found that the higher the skin temperature, the deeper and more severe the tissue damage. Iaizzo et al. found that with temperature as low as 25°C, no ulceration was noted after the skin was loaded with 100 mmHg of pressure for up to ten hours. Human studies by our research team demonstrated a similar protective effect of temperature control on young healthy adults and adults with spinal cord injury. In these studies, skin temperature maintained at 25°C was compared to no temperature control on sacral skin under 60 mmHg of pressure for 30-40 minutes. Blood flow measures showed that the severity of tissue ischemia (determined using magnitude of the reactive hyperemic response) was reduced in both populations when thermal control was applied.

[0008] Only one study was found in the literature that applied local cooling for the purpose of diabetic foot ulcer prevention. This study investigated whether simple cooling of the foot after brisk walking would reduce the temperature to pre-activity level, which may help to reduce the inflammatory response that leads to skin breakdown. They found that the foot skin temperature increased from 79°F to 88°F after 15 minutes of brisk walking for healthy adults. Air cooling (passive) and water cooling (active) methods were applied to the feet after brisk walking, and active water cooling of the feet was able to reduce the skin temperature to pre-activity level right away, while passive air cooling took about 17 minutes to reduce the skin temperature to pre-activity levels. Results of this study indicate that implementing active cooling of the foot is more efficient in reducing temperatures. No studies were identified that investigated the effect of cooling in people with diabetic neuropathy, nor the effect of thermal control applied during mobility and daily activities.

Beneficial impact on the target population

[0009] According to the Diabetic Foot Disorders Clinical Practice Guideline, a multidisciplinary team approach has proven to be the optimal method of treating DFU and lowering the rate of LEA. About 40% of amputation caused by diabetes could be prevented with this multidisciplinary team approach to wound care. Provision of insoles and therapeutic footwear is a crucial part of this multifaceted foot ulcer prevention strategy. Therefore, developing therapeutic footwear that optimizes tissue viability during ambulation and other daily activities will be beneficial in enhancing the health and function of the target population by improving mobility, independence, social participation, and preventing the complications of DFU and subsequent LEA.

[0010] Plantar pressure reduction insoles are currently prescribed to help prevent ulceration by reducing the adverse effect of peripheral ischemia. However, no therapeutic footwear has been developed mainly for the purpose of enhancing tissue viability during repetitive ischemic events (e.g., walking, standing).

[0011] The strong evidence from previous animal and human studies on the benefits of active cooling, and the need for improved prevention of foot ulcers for people with diabetic neuropathy indicates there is benefit in exploring the implementation of active cooling in diabetic footwear. Implementing thermal control features in the insoles of footwear can improve tissue viability during repetitive ischemia, i.e., during ambulation and other activities of daily living, and reduce the risk for developing diabetic foot ulcers.

State-of-the-art in orthotic and thermal diabetic foot care

[0012] Appropriate footwear is an important component of the overall treatment plan for people with diabetes to prevent serious foot complications. Current orthotic intervention consists of specialized insoles and footwear. A diabetic insole, as defined by Medicare, is a total contact, multiple density, removable inlay that is directly molded to the patient's foot or a model of the patient's foot using suitable materials with respect to the individual patient's needs. These insoles must be delivered with an extra depth shoe that is defined as having the following properties; a full-length heel-to-toe filler which when removed provides a minimum of 3/16" additional depth for the insertion of custom-molded or customized insert, made from leather or equivalent material, a shoe closure, and is available in a multitude of sizes with a minimum of three widths. These definitions give the certified orthotist the choice of material selection in order to properly customize the patient's insole. Common materials used in the production of diabetic inserts include open-cell polyurethane foam (PPT™, Poron™), closed-cell expanded rubber (Spenco™), polyethylene thermoplastic foams (Plastazote™), and a variety of other materials of varying mechanical properties. The foam-based materials commonly used in clinical practice have been found to decrease plantar pressure, but were less effective at reducing shear forces than gel-based materials.

[0013] Current devices used in diabetic ulcer prevention and healing include the use of total contact casting, half-shoes, custom insoles, ankle-foot orthoses (AFO), and the Charcot restraint orthotic walker (CROW). The primary goal of these devices is the reduction of plantar pressure through off¬loading of the high-pressure areas, with the goal of decreasing stress on the tissue allowing it to heal. When considering shoe orthoses, the most effective pressure relieving insole is a multi-density insert consisting of a higher density material for support and a less dense material to create good contact with the plantar surface of the user's foot. The higher density material is chosen in order to support the foot in a therapeutic position, which assists with the reduction of pressure. A common technique for relieving areas of high pressure is to modify the insole by replacing the high-density material with less dense material, such as Poron™, under the affected area of the foot. By situating these "plugs" under the current areas of high pressure rather than the area of previous ulceration, improved pressure distribution and reduced areas of high pressure can be achieved; a key factor in diabetic foot ulcer prevention. Specialized insoles for prevention of diabetic foot ulcers are currently being developed with features to relieve excess pressure, warn the user of possible issues, and to measure micro-environmental conditions (e.g., moisture, temperature) of the feet. One such insole is the Smart Insole, patented by Shoureshi and Albert, which focuses on the measurement of temperature, moisture, and pressure in order to warn the user of high risk conditions that can lead to ulceration.

[0014] FIG. 1 shows a traditional extra depth footwear design 10 comprising soft leather 12 padded with foam; an extended heel counter 13, a customized orthotic 14, spacer 15, firm rearfoot board 16, a hidden depth design 17 and a cushioning outsole 18.

[0015] Heating and electric stimulation has been used in diabetic foot care to increase blood flow in areas with injured tissue to promote tissue regeneration. Heating and electric stimulation is viable only for treating ulcers and only when the affected area is completely offloaded to allow unimpeded blood flow. We propose technology innovation through the implementation of cooling in footwear, which focuses on the *prevention* of ulceration while the foot is exposed to loading, as opposed to healing of currently affected areas of the foot. Our prior research has shown that cooling loaded tissue reduces metabolic rate and accumulation of cellular waste products, two factors known to lead to ulceration. This approach has been previously explored in footwear through the use of passive cooling packs, though not implemented in footwear products or clinical practice.

Thermal Control Therapeutic Footwear (TCF)

Description of the need and target population

[0016] The target population of this development project is individuals with diabetic neuropathy who use orthotic footwear and are at risk for diabetic foot ulcers and subsequent amputation. According to the Centers for Disease Control and Prevention, diabetes mellitus affects 25.8 million people, which is about 8.3% of the U.S. population. People with diabetes have a 25% lifetime risk of developing diabetic foot ulcers (DFU). Once an ulcer is formed, about 84% of the cases will proceed to lower extremity amputation (LEA). A study conducted at the Karolinska University Hospital in Sweden reported that 88% of non-traumatic lower extremity amputations were performed due to foot ulceration, confirming the high risk associated with this condition [10].

[0017] In the modern era, a pandemic has reached new levels in the United States: Diabetes. Diabetes, which causes glucose regulation to be hampered in the body, is a set of two distinct diseases. Type 1 diabetes is a disorder that prevents the pancreas from properly producing insulin. Since insulin is responsible for glucose regulation in the body, people who develop this condition cannot regulate their glucose naturally and must use injected insulin to assist their bodies. (Mayo Clinic Staff, 2014a) Type 2 diabetes is commonly a lifestyle disease that can be classified by the body's resistance to insulin or decreased production of insulin, therefore making regulation of the amount of glucose available in the body difficult. (Mayo Clinic Staff, 2014b) This leads to both hypo and hyperglycemia, which are both dangerous acute conditions. However, as regulation of this disease gets better, the long-term effects are becoming more lucid.

[0018] Long-term effects of the body's inability to regulate glucose range from connective tissue changes to neurologic issues in the periphery. (Mayo Clinic Staff, 2014b) One of these potential conditions is the diabetic foot ulcer (DFU). A DFU is defined as "an open sore or wound that occurs in approximately 15 percent of patients with diabetes and is commonly located on the bottom of the foot." (American Podiatric Medical Association, 2015) While this may seem minor, it is one of the most damaging and deadly conditions a diabetic can develop. DFUs, along with other comorbidities such as peripheral arterial disease (PAD), are responsible for the death of 182,000 diabetics yearly. (Mroczek, 2008). With 15% of diabetics developing an ulcer during their lifetime, and an incidence rate of 1% - 4.1% in the population, DFUs are among the most common issue diabetics face, as they get older. (Mroczek, 2008). Along with causing death, DFUs are the number 1 reason for non¬traumatic amputation in the U.S. (Mroczek, 2008). While amputation is often the best course of action and a lifesaving technique, it is not a treatment option that is chosen lightly and has many issues that accompany it as well. As treatments for healing DFUs are constantly improving, the industry of preventing these wounds has remained stagnant and must be further developed and researched.

[0019] Current preventative technology focuses on the management of pressure profiles through the use of specialized footwear and insoles. The entire footwear system is designed to protect the foot from damage that can occur during everyday activities. Extra-depth shoes are designed to provide increased room around the toes to prevent rubbing. Additionally, they have no seams inside the shoe to prevent injury and extra depth allows for a specialized insole to be fitted inside of the footwear. These insoles are designed to move pressure away from the bony prominences of the foot such as the 1st and 2nd metatarsophalangeal (MTP) joint and specials areas of deformations such as those found in Charcot Foot, a disease sometimes present in diabetics which causes the foot to have a rocker bottom deformity. The need for this pressure relief under the MTP joints can be observed due to a majority of DFUs occurring at the forefoot and midfoot. (Tamir, Daniels, Finestone, & Nof, 2007). Treatments are effective if used properly, though misuse or poorly made insoles allow for DFUs to develop even in feet that are well maintained. Due to this, new interventions must be explored to assist with the control of DFUs; one possible intervention is temperature regulation at the high-pressure areas of the foot.

[0020] Temperature has already been shown to have a positive effect on the healing of DFUs through the use of heating. (Petrofsky, Lawson, Berk, & Suh, 2010). The use of cooling to prevent pressure ulcers (PU) is another recent area of interest, and exploring the use of temperature for prevention as well as healing is a worthwhile endeavor. With the goal of preventing an ulcer prior to healing, the risk of infection, amputation, and other complications inherent in a non-healing wound can be reduced. Using cooling to prevent DFUs can be broken down into three possible mechanisms: decreasing in metabolic load, decreasing the reactive hyperemia, and decreasing ischemia in the area being affected. (Kokate et al., 1995). Currently, no one has attempted this method for effective maintenance of tissue integrity, although this method has been proposed in patents with similar designs. (Moreshead, 2012; Vogt, 2012).

[0021] Thus, there is a need for the implementation of advanced technology into everyday practice of DFU prevention. While many different practices have been attempted in healing, including increasing temperature, application of an electrical current through the wound, and using cadaver tissue for bandaging, no realistic methods for DFU prevention outside the use of different materials and the method of pressure reduction have been considered.

[0022] One of the major issues present in diabetic feet is that the damage that occurs causes ischemia that both increases the temperature and pressure under the damaged area. Ischemia is a common biological pathway that happens when tissue takes damage. Ischemia is often associated with moving extra lymphatic fluid towards the site of the tissue damage allowing for better management of the dead tissue. Often this reaction may cause extra damage or discomfort so a common treatment is the application of a cold compress directly to the affected area. Looking at this in a similar manner to a common inflammatory response allows for the assumption that cooling may help to prevent further damage from occurring.

[0023] Pressure is currently the main direct indicator for ulceration in DFUs. Pressure can lead to injury through continuous loading of tissue during gait and acute damage through instantaneous extremely high pressures. Due to trauma being a major contributor for causing ulceration, it is extremely important for clinicians to manage the pressure. In DFUs, this trauma can be caused due to continuous oscillation of pressure on the plantar surface of the foot at specific high pressure areas. Plantar pressure on the feet of diabetic neuropathy patients is much larger than the pressure normally required for the formation of other similar pressure related ulcers. Ulceration can be related to the amount of pressure over time that has been applied to a portion of the body.

[0024] The pressure at the metatarsal phalangeal joints of an ambulatory diabetic neuropathy patient is approximately 100 kilopascals while wearing pressure-relieving footwear and 1000 kilopascals while barefoot. (Petre, Tokar, Kostar, & Cavanagh, 2005). The barefoot pressure of diabetic patients is much higher than non-diabetic patients. This is due to a variety of reasons, although it has much to do with both the pathomechanics of the foot and the tissue changes that occur in diabetics. The pathomechanics of the foot that change the pressure during gait and during stance include the loss of motion at the joints, loss of function of the intrinsic musculature, and extracellular matrix elasticity loss. (Fernando et al, 1991).

[0025] Orthotic interventions for high pressures on the foot are well known and have been developed to redistribute the pressure over more of the foot or to areas of the foot that can take the pressure better. The most common preventative method using pressure is the use of specialized insoles in order to redistribute force. These insoles are often made of three materials placed from lowest durometer to highest durometer. (Van De Weg, Van Der Windt, & Vahl, 2008). This allows for cushioning at the skin interface while giving the foot support to prevent bottoming out of the insole and maintaining good biomechanical position of the foot. Insoles are often customized to patients who have greater risk of ulceration. These custom inserts position indents of lower durometer material under the highest pressure areas of the foot, often under the first and second MTP joints. (Actis et al., 2008). Clinicians can often tell where these high-pressure areas are due to the presence of calluses and skin reddening under these high pressure areas. (Menz et al, 2007).

[0026] The most common method of pressure relief is the excavation of higher durometer material from underneath high-pressure areas and the area filled instead with lower durometer material such as PORON. (Actis et al., 2008). It has been shown that these modifications can reduce pressure by 16-48% under these areas. (Actis et al., 2008). By properly placing these pressure reducing areas, peak pressure on a foot can be decreased by an order of magnitude that can make the difference between whether or not a patient will develop a DFU. (Actis et al., 2008). Failing to place these pressure-reducing areas can lead to increased pressure at the areas of the foot that need relief. Placement and design of these insoles can be done through the use of either foam molds or scanning devices and software.

[0027] It is important to note that custom inserts are only one component of preventative methods. The need for accommodative footwear that is properly sized and modified for the patient is paramount to preventing ulcers at locations away from the plantar surface of the foot. While extra depth footwear is commonly used in diabetic populations, which allows for extra room in the toe box, which prevents rubbing and pressure on the toes, patients with deformation that would make the use of these off the shelf footwear inappropriate require custom footwear fitted to their feet. Another modification that can be done in order to prevent high pressures at the MTPs caused by decreased mobility of the joints of the foot are rocker bottom modifications. (Schaff & Cavanagh, 1990) This modification is based on the idea that without the proper motion at the joints of the foot, pressure will move from the heel to the forefoot. Rocker bottoms allow for a more natural rollover occurs during gait causing these unnatural pressures to be dissipated.

[0028] Considering these modifications and orthotics used, there is still a fairly significant failure to prevent ulcers using these devices. Over time it is 15% likely that a diabetic patient will develop an ulcer that can become life threatening. (Mroczek, 2008) Considering this, inspiration must come from similar fields that can lend their knowledge base. One such concept taken from pressure ulcer research is the use of temperature in order to prevent ulceration from occurring. Through the use of local cooling, pressure has been found to be somewhat negated when a lower temperature has been reached in the tissue. As presented before, the mechanisms of prevention through cooling aim at affecting the tissue through both metabolic and biomechanical changes. The tissue changes that occur in diabetes cause some of these treatments to be less effective while others become more needed. The two big problems diabetics face that can be affected by cooling consist of metabolic changes of tissue and temperature regulation.

[0029] Metabolic issues especially occur in the diabetic population due to the changes to glucose regulation and levels in the body. (Mayo Clinic Staff, 2014b) Decreasing temperature has been shown to decrease the metabolic rate. (Kokate et al., 1995) Using this concept, cooling tissue that has a decreased blood supply can be related to cooling the body to reduce necrosis of tissue during surgeries. (Kokate et al., 1995) Temperature regulation has been found to be a major issue for diabetics due to neurological changes that occur due to diabetic neuropathy. One of the most obvious effects of lack of temperature control is the lack of sweating at increased temperature.

[0030] Thus, there exists a need for a TCF that adds cooling functionality to a pressure-reducing surface of the foot bed.

SUMMARY

[0031] One aspect of a preferred embodiment of the present disclosure comprises a footwear product with an integrated active temperature control system comprising: an upper; a sole comprising an insole comprising one or more thermo-conductive inserts or plugs; a midsole disposed between the insole and an outsole; wherein the midsole comprises one or more cooling elements selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element; and one or more heat sinks disposed in the midsole, outsole or between the midsole and outsole.

[0032] In another aspect of a preferred footwear product of the present disclosure, the thermo-conductive inserts or plugs comprise one or more materials selected from the group consisting of a gel, an open-cell polyurethane foam, a closed-cell expanded rubber, a low friction interface material, and a polyethylene thermoplastic foam.

[0033] In yet another aspect of a preferred footwear product of the present disclosure, a separate one of the one or more cooling elements is disposed adjacent to or underneath each of the one or more the thermo-conductive inserts or plugs.

[0034] In another aspect of a preferred footwear product of the present disclosure, each of the one or more cooling elements comprises an active solid-state electrical device.

[0035] In an additional aspect of a preferred footwear product of the present disclosure, each of the one or more cooling elements comprises a thermo-electric cooling element having an active solid-state electrical device that operates on the Peltier effect.

[0036] In another aspect, a preferred footwear product of the present disclosure further comprises a power source for the one or more cooling elements.

[0037] In another aspect of a preferred footwear product of the present disclosure, the power source comprises rechargeable batteries that may be recharged when in use and/or when not in use.

[0038] In another aspect, a preferred footwear product of the present disclosure further comprises a control system or a closed loop passive control system to control the amount of heat being removed from the footwear product.

[0039] In yet another aspect of a preferred footwear product of the present disclosure, the one or more thermo-conductive inserts or plugs also provide cushioning to control pressure and/or shear and are each disposed in a portion of the insole contacting a high-pressure area or other area of the plantar surface of a foot disposed in the footwear product that normally experiences tissue breakdown, such as the first metatarsal or heel.

[0040] In another aspect, a preferred footwear product of the present disclosure further comprises a power source for the one or more heat sinks.

[0041] In yet another aspect of a preferred footwear product of the present disclosure, the one or more heat sinks are passive or body-powered.

[0042] In yet another aspect of a preferred footwear product of the present disclosure, each of the one or more heat sinks employs an air movement system that uses convection to move heat from each heat sink into the environment outside of the footwear product.

[0043] In a further aspect of a preferred footwear product of the present disclosure, each of the one or more heat sinks employs the loading and/or unloading of the sole during gait to create airflow through or across each heat sink to move heat from each heat sink into the environment outside of the footwear product.

[0044] In another aspect, a preferred footwear product of the present disclosure further comprises temperature and/or pressure sensor(s) associated with each of the one or more thermo-conductive inserts or plugs.

[0045] In yet another aspect, a preferred footwear product of the present disclosure further comprises a control system or CPU to control the amount of heat being removed from the footwear product; wherein the control system or CPU has an input for setting the temperature to be maintained or to not be exceeded at each location of the one or more thermo-conductive inserts or plugs.

[0046] In a further aspect of a preferred footwear product of the present disclosure, the input is disposed inside or outside of the footwear product and/or is operatively connected wirelessly or by wire to the control system.

[0047] In another aspect of a preferred footwear product of the present disclosure, the integrated active temperature control system is activated upon exceeding a preset pressure on one or more of the pressure sensors.

[0048] In a further aspect of a preferred footwear product of the present disclosure, each of the one or more heat sinks comprises a metal component and/or a thermal-conductive foam component.

[0049] In another aspect of a preferred footwear product of the present disclosure, a single heat sink comprises one or more metal components and/or a thermal-conductive foam components and wherein the single heat sink directly contacts each of the one or more thermo-electric cooling elements.

[0050] Another aspect of a preferred embodiment of the present disclosure comprises a kit for retrofitting a footwear product to include an integrated active temperature control system, wherein the kit comprises one or more of the following items: a plug, having an upper surface comprising a low friction interface material and comprising a thermally conductive material, wherein the plug is for placement in an opening in an existing insole, a heat sink and cooling device for placement in the midsole and/or outer sole of the footwear product and a thermal paste or adhesive for connecting the thermal conductive material of the plug to the cooling device and/or heat sink.

[0051] In another aspect of a preferred kit of the present disclosure, the cooling device is selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element.

[0052] In a further aspect of a preferred kit of the present disclosure, the plug comprises one or more materials selected from the group consisting of: a gel, an open-cell polyurethane foam, a closed-cell expanded rubber, a cushioning material and a polyethylene thermoplastic foam.

[0053] In another aspect of a of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0054] The present disclosure is illustrated by way of example and not limitation in the figures of the accompanying drawings, in which:

[0055] **FIG. 1** shows a traditional extra depth footwear design;

[0056] **FIG. 2** is a cross-sectional view of a preferred embodiment of a footwear product with an integrated active temperature control system according to the present disclosure;

[0057] **FIG. 3** is a cross-sectional view with heat flow diagram of a preferred embodiment of a footwear product with an integrated active temperature control system according to the present disclosure; and

[0058] **FIG. 4** is a diagram of a control circuit for a preferred embodiment of a footwear product with an integrated active temperature control system according to the present disclosure.

DETAILED DESCRIPTION

[0059] In the following detailed description, reference is made to the accompanying examples and figures that form a part hereof, and in which is shown by way of illustration specific embodiments in which the inventive subject matter may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice them, and it is to be understood that other embodiments may be utilized and that structural, logical, and electrical changes may be made without departing from the scope of the inventive subject matter. Such embodiments of the inventive subject matter may be referred to, individually and/or collectively, herein by the term "disclosure" merely for convenience and without intending to voluntarily limit the scope of this application to any single disclosure or inventive concept if more than one is in fact disclosed.

[0060] The following description is, therefore, not to be taken in a limited sense, and the scope of this disclosure is defined by the appended claims.

[0061] A preferred embodiment of a temperature control therapeutic footwear (TCF) of the present disclosure comprises one or more coolers 35, heat sink 32, insole material 25 and, in various embodiments, a plug 40 and control circuit (as shown in FIG. 4).

[0062] Preferably, cooler 35 will be a thermoelectric cooler which uses the Peltier effect in order to transform a voltage differential into a temperature differential. Thermoelectric coolers are relatively thin, light yet durable, are able to be controlled accurately, operate over the desired temperature range, and durability. Each thermoelectric cooler 35 is mated to a heat sink 32 to manage any bleed through of heat.

[0063] Preferably, heat sink 32 will act to effect adequate removal of heat from the thermoelectric cooler 35, release of heat into the external environment, and be of minimal weight. Heat sink 32 preferably will not affect the gait of the wearer and be durable. Preferably, heat sink 32 will be made of aluminum or other suitable metal or material. The TCF 20 of the present disclosure preferably has an open air system into the sole 23 which comprises insole 25, midsole 26 and outsole 27 to allow for good airflow and convection to occur at the heat sink 32. Thermoelectric cooler 35 will preferably be attached to heat sink 32 using thermo-conductive adhesive that is commonly used with CPUs and heat sinks in high end computers.

[0064] Material for insole 25 and plug 40 are an integral portion of this design because they are in direct contact with the wearer. Plug material preferably is thermo-conductive while having a low durometer in order to accommodate the increased pressure under the high pressure areas, such as the MTPs or under deformities. Additionally, insole material should be machinable and easy to implant in order for practitioners or manufacturers to be able to custom place the devices for each wearer.

[0065] Preferably, the control circuit of the TCF 20 is programmable to allow for targeted temperature, as well as to provide energy conservation. A preferred control circuit of the TCF 20 is easily calibrated in order to account for weight, resting body temperature, other disease considerations that may affect the pressure or temperature setting for TCF 20. The control circuit of TCF 20 also preferably is small and requires minimal energy to operate.

[0066] Preferably, TCF 20 of the present disclosure is customizable for each individual wearer. Preferably, the TCF 20 is customizable via on site tools and may also comprise a heat sink incorporated into the outer sole 27 to effectively dissipate heat from TCF 20.

[0067] As seen in **FIGS. 2 and 3,** the foot is in contact with a thermo-conductive plug 40 that is placed under a clinician-selected location within TCF 20. Plug 40 preferably comprises an upper surface 33 comprising a low friction interface material manufactured with polytetrafluoroethylene (PTFE) film, such as ShearBan®, to protect the wearer's skin from damaging friction & shear trauma. Additionally, plug 40 comprises a cushioning pad 28 (preferably of a gel) and cooler 35 and heat sink 32 may also be incorporated into plug 40 in various preferred embodiments of TCF 20. Alternatively, heat sink 32 is disposed in or part of outer sole 27. TCF 20 moves the heat away from the foot towards outer sole 27 allowing for therapeutic temperature control at the high-pressure areas of the foot. The arrows in FIG. 3 show a preferred heat flow diagram accomplished by TCF 20.

[0068] The thermo-conductive plug 40 preferably will consist of an easily machinable material, such as EVA, along with good heat conductors such as thermo-conductive gels. This will allow for the plug to be placed and fitted into a specific area of the foot, while keeping the conductive qualities that are needed. The placement of the plug 40 will be conducted using the current method of excavating the higher durometer material from the bottom of the material and then adhering the new lower durometer material to fill the location. This method allows for a customizable cooling plug 40 that can be specifically placed by the practitioner without much difficulty. By designing the heat sink 32 with the goal of adjustability of the location of plug 40, a variety of sizes or adjustability of the heat sink 32 can allow for relatively easy customization.

[0069] TCF 20 preferably comprises diabetic footwear technology that prevents ischemic damage and subsequent diabetic foot ulcer development. Maintaining skin temperature at lower levels where high-pressure occludes blood flow minimizes ischemic damage. TCF 20 preferably maintains skin temperature at select locations of the foot at pre-activity levels during activity and after extended use.

[0070] *Insole.* The whole insole 25 is preferably made of thermal insulate materials, and thermo conductive gel pads 28 are preferably placed at the high-pressure areas, e.g., first metatarsal, and heel. By using controlled localized cooling it is possible to give therapeutic cooling to the needed areas while not affecting the rest of the foot.

[0071] *Midsole.* Cooling elements 35 such as phase change cooling (cooling packs), passive cooling (heat sink only), air flow cooling (fans, etc.), liquid cooling, Peltier (thermoelectric coolers), heat pipe systems or the like will be placed at the same locations as the gel pads 28 (and may preferably comprise part of plug 40) to maintain the temperature. Preferably, the thermoelectric cooling elements 35 are active solid-state electrical modules that operate on the Peltier effect, which is a phenomenon whereby the passage of an electrical current through a junction consisting of two dissimilar metals results in a cooling effect. Preferably, cooling elements 35 use rechargeable batteries as a power source whereby the user would recharge TCF 20 when not in use. Preferably, a closed loop passive control system will be used to control the amount of heat being removed from the plantar surface of the foot by TCF 20. This will act as a safety and energy conservation mechanism.

[0072] *Outsole.* A heat sink 32 preferably will be used to move the heat away from the one or more thermoelectric coolers 35. Preferably, heat sinks 32 will either be a passive or a body-powered device. In a preferred embodiment, heat sink 32 comprises a gait-powered air movement system that would use convection to move heat from the heat sink 32 into the environment outside of TCF 20. Such a heat sink 32 would use the loading and unloading of the footwear during gait to create airflow through the heat sink 32.

[0073] The present disclosure also contemplates a kit for retrofitting a footwear product, such as a diabetic footwear product, to include an integrated active temperature control system, wherein the kit comprises one or more of the following items: a soft material plug 40 having an upper surface 33 comprising a low friction interface material manufactured with polytetrafluoroethylene (PTFE) film and a thermal conductive core 28 that can be placed into an existing insole, a heat sink 32 and cooling device 35 that will preferably be placed inside the outer sole 27 of TCF 20 and will be connected to the thermal conductive material 28 via thermal paste or adhesive.

[0074] It should be understood that while this disclosure has been described herein in terms of specific, preferred embodiments set forth in detail, such embodiments are presented by way of illustration of the general principles of the disclosure, and the disclosure is not necessarily limited thereto. Certain modifications and variations in any given material, process step or chemical formula will be readily apparent to those skilled in the art without departing from the true spirit and scope of the present disclosure, and all such modifications and variations should be considered within the scope of the claims that follow.

What is claimed is:

1. A footwear product with an integrated active temperature control system comprising:
an upper;
a sole comprising an insole comprising one or more thermo-conductive inserts or plugs;
a midsole disposed between the insole and an outsole;
wherein the midsole comprises one or more cooling elements selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element; and
one or more heat sinks disposed in the midsole, outsole or between the midsole and outsole.

2. The footwear product of claim 1 wherein the thermo-conductive inserts or plugs comprise one or more materials selected from the group consisting of a gel, an open-cell polyurethane foam, a closed-cell expanded rubber, a low friction interface material, and a polyethylene thermoplastic foam.

3. The footwear product of claim 1 wherein a separate one of the one or more cooling elements is disposed adjacent to or underneath each of the one or more the thermo-conductive inserts or plugs.

4. The footwear product of claim 1 wherein each of the one or more cooling elements comprises an active solid-state electrical device.

5. The footwear product of claim 1 wherein each of the one or more cooling elements comprises a thermo-electric cooling element having an active solid-state electrical device that operates on the Peltier effect.

6. The footwear product of claim 1 further comprising a power source for the one or more cooling elements.

7. The footwear product of claim 6 wherein the power source comprises rechargeable batteries that may be recharged when in use and/or when not in use.

8. The footwear product of claim 1 further comprising a control system or a closed loop passive control system to control the amount of heat being removed from the footwear product.

9. The footwear product of claim 1 wherein the one or more thermo-conductive inserts or plugs also provide cushioning to control pressure and/or shear and are each disposed in a

portion of the insole contacting a high-pressure area or other area of the plantar surface of a foot disposed in the footwear product that normally experiences tissue breakdown, such as the first metatarsal or heel.

10. The footwear product of claim 1 further comprising a power source for the one or more heat sinks.

11. The footwear product of claim 1 wherein the one or more heat sinks are passive or body-powered.

12. The footwear product of claim 1 wherein each of the one or more heat sinks employs an air movement system that uses convection to move heat from each heat sink into the environment outside of the footwear product.

13. The footwear product of claim 1 wherein each of the one or more heat sinks employs the loading and/or unloading of the sole during gait to create airflow through or across each heat sink to move heat from each heat sink into the environment outside of the footwear product.

14. The footwear product of claim 1 further comprising temperature and/or pressure sensor(s) associated with each of the one or more thermo-conductive inserts or plugs.

15. The footwear product of claim 14 further comprising a control system or CPU to control the amount of heat being removed from the footwear product; wherein the control system or CPU has an input for setting the temperature to be maintained or to not be exceeded at each location of the one or more thermo-conductive inserts or plugs.

16. The footwear product of claim 15 wherein the input is disposed inside or outside of the footwear product and/or is operatively connected wirelessly or by wire to the control system.

17. The footwear product of claim 15 wherein the integrated active temperature control system is activated upon exceeding a preset pressure on one or more of the pressure sensors.

18. The footwear product of claim 1 wherein each of the one or more heat sinks comprises a metal component and/or a thermal-conductive foam component.

19. The footwear product of claim 1 wherein a single heat sink comprises one or more metal components and/or a thermal-conductive foam components and wherein the single heat sink directly contacts each of the one or more thermo-electric cooling elements.

20. A kit for retrofitting a footwear product to include an integrated active temperature control system, wherein the kit comprises one or more of the following items: a plug, having an upper surface comprising a low friction interface material and comprising a thermally conductive material, wherein the plug is for placement in an opening in an existing insole, a heat sink and cooling device for placement in the midsole and/or outer sole of the footwear product and a thermal paste or adhesive for connecting the thermal conductive material of the plug to the cooling device and/or heat sink.

21. The kit of claim 20 wherein the cooling device is selected from the group consisting of: an air flow cooling element, a liquid cooling element, a thermoelectric cooling element.

22. The kit of claim 20 wherein the plug comprises one or more materials selected from the group consisting of: a gel, an open-cell polyurethane foam, a closed-cell expanded rubber, a cushioning material and a polyethylene thermoplastic foam.

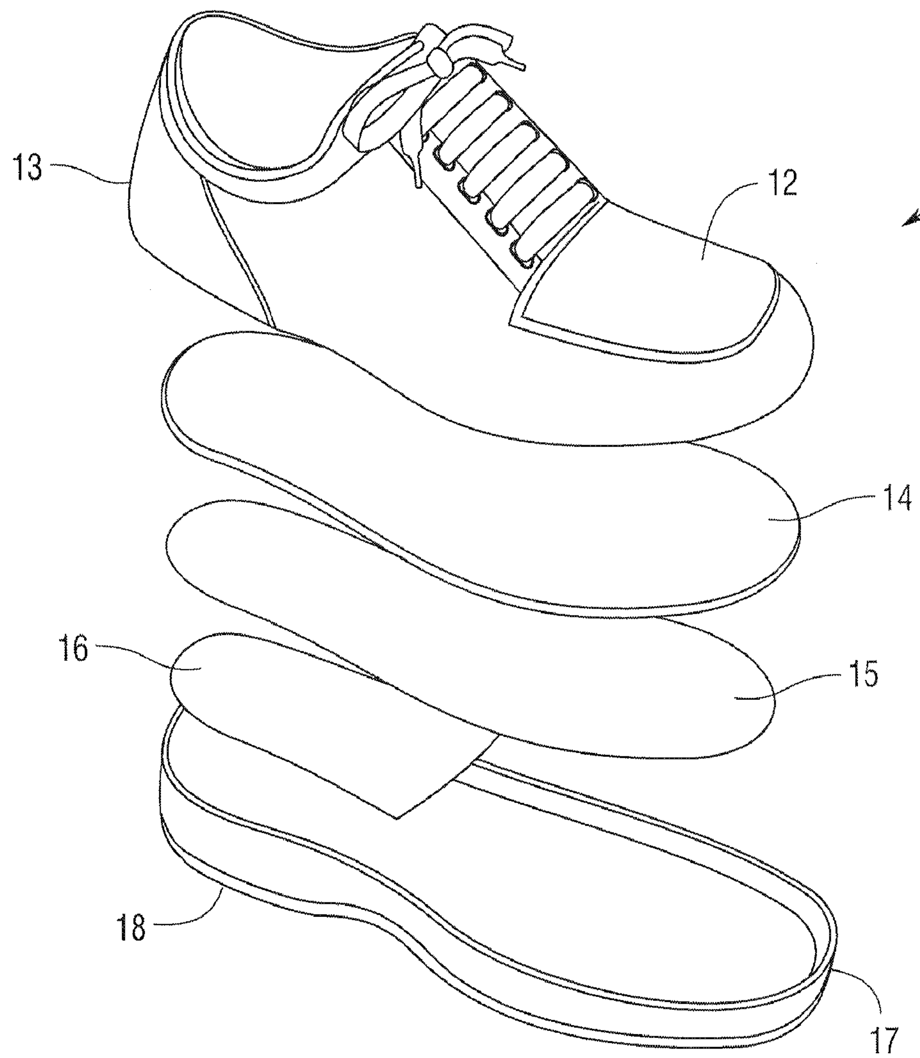

Fig.1

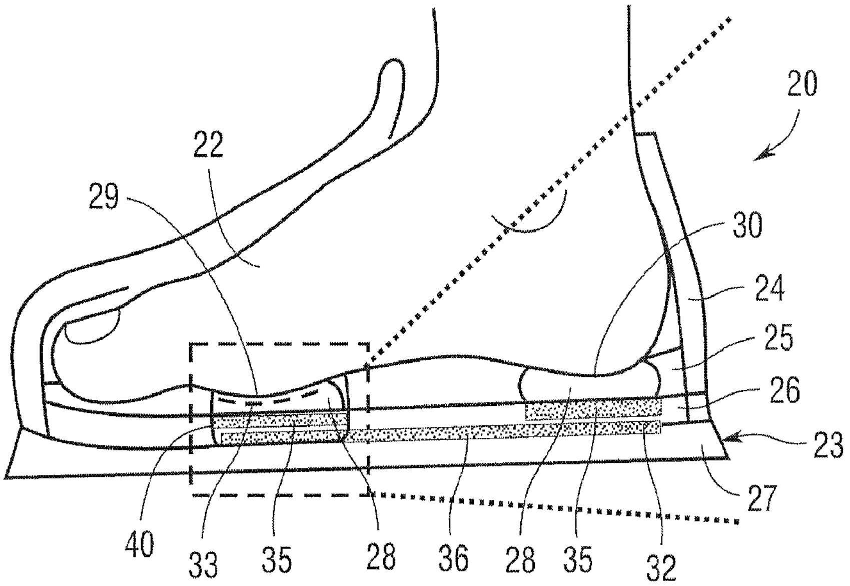
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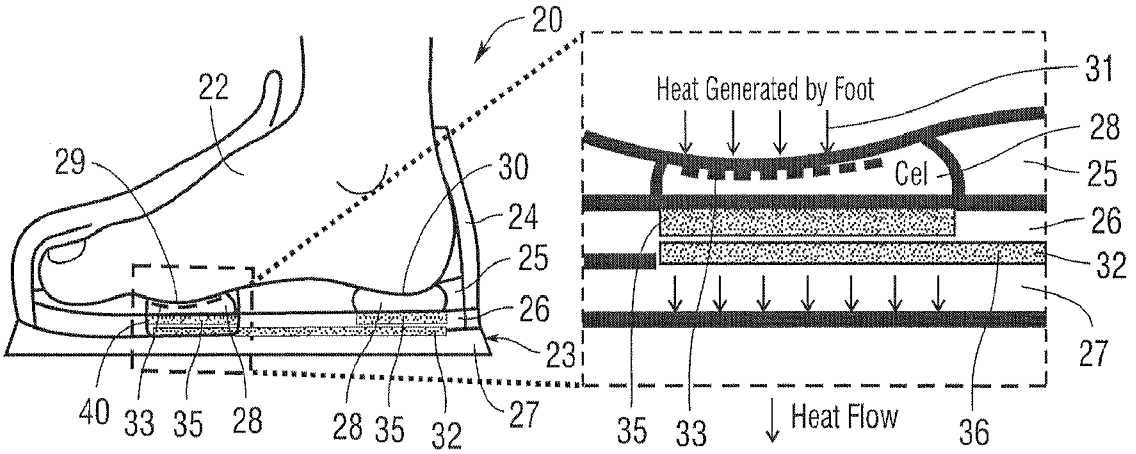
Fig.2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Cel
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Heat Flow
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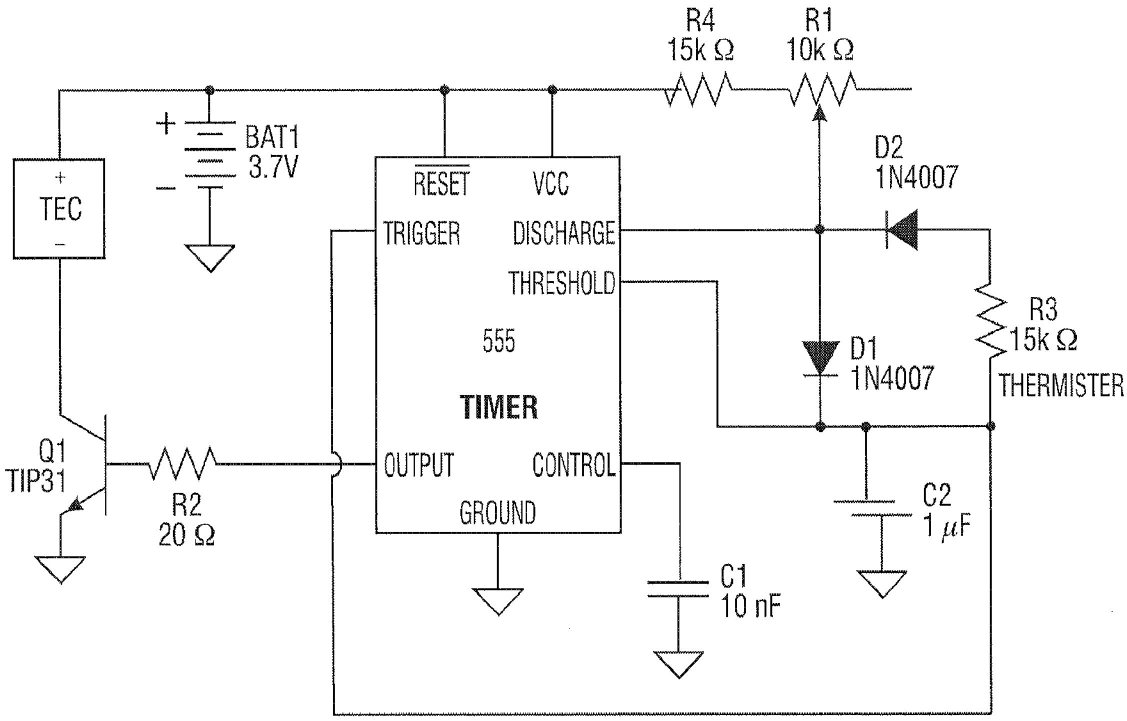
Fig.3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15k Ω
R1
10k Ω
BAT1
3.7V
TEC
RESET
VCC
D2
1N4007
TRIGGER
DISCHARGE
THRESHOLD
555
TIMER
R3
15k Ω
THERMISTER
D1
1N4007
Q1
TIP31
R2
20 Ω
OUTPUT
CONTROL
GROUND
C2
1 µF
C1
10 nF

Fig.4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/055776

A. CLASSIFICATION OF SUBJECT MATTER

A43B 7/00(2006.01)i, A43B 7/04(2006.01)i, A43B 3/00(2006.01)i, A43B 17/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A43B 7/00; A43B 7/34; A43B 7/06; A43B 13/38; F25B 21/02; A43B 17/02; A43B 17/08; A43B 7/04; A43B 3/00; A43B 17/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: cooling element, heat sink, sole, cushioning, peltier effect, sensor, control, footwear

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	W0 2010-085163 Al (CTCP-CENTRO TECNOLOGICO DO CALCADO DE PORTUGAL et al.) 29 July 2010 See abstract; claims 1, 3, 5; pages 8, 10, 11; and figures 1-6.	1-22
Y	US 2013-0019503 Al (VOGT, BRIAN JAMES) 24 January 2013 See abstract; claims 1, 14, 16; paragraphs [0044]-[0046], [0052]; and figures 4A-5B.	1-22
Y	US 2008-0271340 Al (GRISONI, BERNARD F. et al.) 06 November 2008 See abstract; claims 2-5; and figures 1-5.	2,9,22
A	KR 10-2015-0003535 A (BAE, SANG WON) 09 January 2015 See abstract; claims 1-4; and figures 2-6.	1-22
A	WO 2013-054999 Al (Y00, SUNG YEUB) 18 April 2013 See abstract; claims 1-6; and figures 1-8.	1-22

☐ Further documents are listed in the continuation of Box C. ☒ 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	Date of mailing of the international search report
09 January 2017 (09.01.2017)	**11 January 2017 (11.01.2017)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/055776

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		US 2013-0042502 Al	21/02/2013
		WO 2008-019084 A2	14/02/2008
		WO 2008-019084 A3	10/07/2008
KR 10-2015-0003535 A	09/01/2015	None	
WO 2013-054999 Al	18/04/2013	KR 10-1136110 Bl	17/04/2012