Abstract:
The present invention relates to devices, methods and systems for tracking and monitoring vital signs and for early detection of various diseases and conditions in an ungulate mammal, as well as for continuous monitoring the mammal’s health condition.
DEVICE AND SYSTEM FOR EARLY DETECTION AND MONITORING VARIOUS DISEASES AND CONDITIONS OF AN UNGULATE MAMMAL

FIELD OF THE INVENTION
[0001] The present invention relates to devices, methods and systems for the early detection of various diseases and conditions in an ungulate mammal, such as a horse, as well as for continuous monitoring the mammal's health condition.

BACKGROUND OF THE INVENTION
[0002] Horses are well adapted to running and labor. However, their unique physical properties that contribute to their abilities are also the reason for many of the horse's diseases and harmful conditions- especially those involving their legs and feet. Laminitis, Navicular Disease, Quarter cracks, tendonitis, and infections, such as Thrush and Quiltor as well as colic, are examples of such conditions and other diseases. These conditions and disease can also affect other ungulate mammals, such as cattle, camels, etc.

[0003] Laminitis is an example of a serious harmful condition that affects horses of all breeds, ages and genders throughout the world. It is a common, painful, and potentially disastrous condition of the horse's foot. The disease affects the tissues that attach the hoof wall to the coffin bone within the hoof capsule. Laminitis is a failure of the attachment between the distal phalanx (coffin bone) and the inner hoof wall, caused by inflammation of the laminae: The lamellae of the inner hoof wall attaches the distal phalanx from the inner surface of the hoof capsule, and when this connection fails, the horse suffer from laminitis. When the distal phalanx is not properly attached to the inside of the hoof, the weight of the horse and the forces of locomotion force the bone down into the hoof capsule, damaging the surrounding tissues, including arteries and veins, the sole and the coronet, thereby causing immense pain and a characteristic lameness.

[0004] Laminitis is a potentially fatal disease due to the persistence and severity of pain, and the structural damage that occurs in affected ungulate mammals such as horses. Horses that survive an acute episode of laminitis frequently require long-term management and are predisposed to recurrent episodes.

[0005] When considering laminitis, two points are examined: (i) the attachment of the coffin bone to the hoof; and (ii) the blood supply to the foot. The coffin bone, which is the main bone of the foot, provides the horse's foot the required rigidity for bearing the horse's
weight. It is actually suspended in the hoof, attached by a Velcro-like arrangement of specialized structures, called laminae, to the inside of the hoofs wall. Thus, the laminae hold the hoof wall onto the coffin bone.

Dermal laminae grow outwards from the laminar dermis attached to the coffin bone, and in addition to attaching the coffin bone to the hoof wall, the laminar dermal region also (i) contains sensory nerves that inform the horse about the position of its hoof, (ii) involved in thermo-regulation, and (iii) contains blood vessels that nourish the hoof and allow its growth.

Blood supply to the equine foot is unusual: in addition to the normal arteries-capillaries-veins circulation, the equine foot also has arteriovenous shunts, which allow the arterial blood to go directly to the veins, bypassing the capillaries. When these shunts are open, little or no blood is going to the tissues. The shunts are thought to protect the capillaries from unduly high blood pressure.

Laminitis usually develops as a result of a variety of seemingly unrelated pathological events occurring elsewhere in the horse's body. This makes the identification of laminitis extremely hard, if not impossible.

Laminitis is divided into four phases: the developmental phase; the acute phase; the sub-acute phase; and the chronic phase. Treatment and prognosis of laminitis is depended on the phase of the disease, wherein animals that are treated at an earlier stage often present better prognosis. Thus, it is desirable to detect laminitis as early as possible. Accordingly, a need exists for means to easily monitoring the early occurrence of laminitis in order to avoid irreversible damage and improve prognosis.

Laminitis starts in a prodromal or developmental phase, when the pathological lamellar changes start, and lasts for about 24 to 48 hours, in which the first clinical signs might be detected. The acute phase of laminitis begins together with the onset of clinical signs and starts anywhere from 24 to 72 hours after the initial damage to the basement membrane. This phase is expressed by visible clinical signs, such as increased hoof temperature, increased digital pulse and lameness. The acute phase ends with the displacement of the distal phalanx and/or following 72 hours of pain. Then begins the chronic phase of laminitis.

Acute laminitis, e.g. in horses and cows, is characterized by some or all of the following signs: (i) turning in circles or reluctance to move; (ii) heat in the feet; (iii) increased digital pulse in the feet; (iv) pain in the toe region when pressure is applied with
hoof testers; (v) reluctant or hesitant gait ("walking on eggshells"); (vi) a "sawhorse stance" (front feet stretched out in front to alleviate pressure on the foot); and (vii) systemic changes: anorexia, anxiety, increased respiration and pulse rates.

[0012] After 72 hours of lameness or after the rotation and/or sinking of the coffin bone due to the separation of the laminae at the front of the foot, laminitis is considered as "chronic laminitis". Chronic laminitis is characterized by the following signs: (i) rings in hoof wall that become wider as they are followed from toe to heel; (ii) bruised soles or "stone bruises"; (iii) widened white line ("seedy toe") with blood pockets and/or abscesses; (iv) dropped soles or flat feet; (v) thick, "cresty" neck; and (vi) dished hooves (due to unequal hoof growth rates).

[0013] In acute and severe laminitis, diagnosis is usually straightforward and is based on the history and posture of the horse, increased temperature of the hooves, a bounding pulse in the digital arteries, as well as a reluctance to move. Gross observation and distinct measurements of radiographs of the foot enable determining the severity of laminitis, e.g. by evaluating whether distal displacement, rotation, both distal displacement and rotation, or unilateral sinking has occurred. However, diagnosis in those methods enables identifying laminitis only after it occurs, and in many cases when irreversible damage has already happened.

[0014] Acute laminitis constitutes a medical emergency since phalangeal displacement might occur rapidly. Despite prompt therapy, the prognosis is guarded until recovery is complete and it is evident that the hoof architecture is not altered. In addition, in order to reduce inflammation in the prodromal and acute phases of laminitis, non-inflammatory agents, such as NSAID, lidocaine and dimethyl sulfoxide, are usually administered.

[0015] Laminitis therapy includes cryotherapy (mainly at early stages), medications (for pain and infections), and surgery. However, recovery from laminitis is unpredictable, and prognosis is directly proportional to the extent of displacement of the distal phalanx and the resultant lamellar pathology that occurs. Prognosis is also highly affected by early identification and treatment. Although few horses return to normal athletic soundness after chronic laminitis, most make only partial recovery and often suffer from intermitted lameness or recurrent episodes of foot pain.

[0016] Some horses that show the clinical signs of acute laminitis recover completely if treated promptly using a combination of rational medical therapy and mechanical support. However, horses recovering from even the mildest laminitis should be rested and observed
closely to prevent recurrent episodes. Each episode requires months of expensive supportive care and surgery and although surprising recoveries happen, most animals suffer months of crippling foot pain.

[0017] Temperature elevation and increased digital pulse in the horse's foot have been demonstrated during laminitis. Notably, hoof temperature is not a constant value and it changes during the day according to the horse's physical activity and physiological condition. However, prolonged hoof temperatures of over 30°C (i.e. more than 24 hours) may indicate impending laminitis. Hoofs temperature and hoof surface's temperature have been examined as possible indications and alerts of different conditions of the hoof. Similarly, blood flow in the digit artery has also been examined as possible assessment of the horse's condition. Examples of such studies are Worster et al., 2000; Buchner and Wiesenhofer, 2011; and Bailey et al., 2004. However, none of the setups, devices and methods described in these (and other studies) could be used for long term monitoring or in the everyday surrounding of the tested ungulate mammals, e.g. horses.

[0018] US 2008/0202445, WO 2006/015372, WO 2006/053290, US 2006/0000420, US 6,532,901 and US 6,436,038, describe different devices and methods for monitoring various conditions in animals. US 2005/0177063 provides a hoof temperature sensor. WO 2008/011590 and EP 1997075 provide sensors and methods for the detection of lameness. WO 2006/009959 describes a method and a device for evaluating animals' health. However, all of the setups, devices and methods described in these (and other) publications suffer from various disadvantages, such as movement limitation of the evaluated animal, the number of possible measurements taken, insufficient continuity data, etc.

[0019] Thus, a need exists for a simple and easy-to-use device, that can be placed onto evaluated/tested ungulate mammals, e.g. on their leg, limb, foot, etc., which will not interfere with the animal's routine and everyday activity, and which will be able to provide continuous data on the animal's different health parameters, such as temperature, blood flow, pulse, etc. The device of the present invention provides all of these and more.
SUMMARY OF THE INVENTION

[0020] In certain embodiments, the present invention provides a device for early
detection of inflammatory conditions or injury and/or for monitoring the recurrence or
severity of laminitis or any other inflammatory condition or injury in an ungulate mammal's
foot, said device comprising: (i) at least one sensor; (ii) a power source; and (iii) a
transmitter, wherein said device is designed to be placed onto the ungulate mammal's foot,
hoof, or both, for continuous or periodic monitoring the condition of the ungulate mammal's
foot, without disturbing its daily activity.

[0021] It should be noted that the term "foot" as used herein refers to any part of the
animal's foot or limb, including: leg, hoof, coronet band, distal phalanges, cartilage, sole,
etc., and any combination thereof.

[0022] In certain embodiments, the present invention provides a system for early
detecting, continuously or periodically monitoring and alerting the occurrence, progression
and/or the severity of an inflammatory condition or injury in an ungulate mammal's foot,
said system comprising: (i) the device of the invention; (ii) a computer comprising a
processor and a memory, coupled to said device, adapted to receive data from sensor(s) in
said device, and designed to analyze said data; and (iii) an alert module in said computer
adapted for producing an alert if said analyzed data is determined to indicate a possible
inflammation condition or injury.

[0023] In certain embodiments, the present invention provides a method for early
detecting the onset of an inflammatory condition or injury in an ungulate mammal's foot,
said method comprising: (a) placing or attaching a device of the invention onto the ungulate
mammal's body, e.g., at least one of its feet/hoofs, neck, chest, etc.; (b) monitoring the basal
conditions of the ungulate mammal for a predetermined period of time, thereby creating
reference conditions; (c) continuously or periodically measuring different parameters in each
of the ungulate mammal's feet; (d) continuously or periodically comparing the measured
parameters to the reference conditions; (e) continuously or periodically calculating the
differences between said measured parameters and reference conditions; (f) determining
whether said calculated differences are indicative of occurrence of an inflammatory
condition or injury based on any combination of various parameters such as: basal
conditions, ambient / environment state (e.g. ambient temperature), latest activity, past
diseases or injuries, similar changes in other horses, etc.; and (g) presenting the
determination and/or the calculated differences and/or alerting the ungulate mammal's owner.
of the ungulate mammal's condition, wherein said device in step (a) remains on the ungulate mammal's feet without disturbing the ungulate mammal's daily activity, thereby enabling early detection of an inflammatory condition or injury for improving prognosis.

[0024] In certain embodiments, the present invention provides a method for continuously monitoring and alerting the occurrence, recurrence and/or severity of laminitis in a horse's foot, said method comprising: (a) placing or attaching a device of the invention onto each of the horse's four feet/hoofs; (b) monitoring the current conditions of the horse for a predetermined period of time, thereby creating reference conditions; (c) continuously and/or periodically measuring different parameters in each of the horse's feet; (d) continuously and/or periodically comparing the measured parameters to the reference conditions; (e) continuously and/or periodically calculating the differences between said measured parameters and reference conditions; (f) determining whether said calculated differences are indicative of recurrence of laminitis or whether the laminitis condition is worsen or improves; and (g) presenting said determination of step (f) and/or the calculated differences of step (e) and/or alerting the horse's owner of the horse's condition, wherein said device in step (a) remains on the horse's feet without disturbing the horse's daily activity, thereby enabling continuously monitoring and alerting the recurrence and/or the severity of laminitis for improving prognosis.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Figs. 1A-1B illustrate the device of the invention: Fig. 1A is a schematic drawing of the device; and Fig. 1B is an illustration of one configuration of the device suitable for placing directly onto the animal hoof.

[0026] Fig. 2 is a schematic drawing of the system of the invention with a device of the invention placed on each of a horse's foot.

[0027] Figs. 3A-3C are graphs showing horse's temperature fluctuation over time.

[0028] Fig. 4 is a block diagram describing the online feature of the system of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0029] It is well known that early diagnosis of diseases and conditions improves prognosis and reduces healing times of various diseases and medical conditions. This applies also to ungulate mammal's diseases and medical conditions, and is extremely important in
the case of laminitis and other foot disorders of horses, cows, etc., which are always standing.

[0030] The present invention provides a novel device which enables long term and continuous monitoring of the tested ungulate mammal (e.g. horse, cow, etc.), in order to facilitate preventative treatment for colic. It has been shown that temperature, pulse, and blood flow measurements are reliable diagnostic tools for colic, and therefore continuous monitoring thereof is highly beneficial in determining the animal's health condition.

[0031] The present invention further provides a novel device which enables long term and continuous monitoring of the tested ungulate mammal (e.g. horse, cow, etc.), in order to facilitate preventative treatment for laminitis and/or other inflammatory diseases and conditions, such as inflammatory injuries. It has been shown that temperature, pulse, and blood flow measurements are reliable diagnostic tools for several diseases, including laminitis, tendonitis, and colic, and therefore continuous monitoring thereof is highly beneficial in determining the animal's health condition.

[0032] In addition, the present invention provides a novel method for monitoring the animal's condition and health, using unique data comparison between (i) baseline data and the measured data, and/or (ii) data gathered from each of the monitored areas on/in the tested mammal, such as the limbs, neck, chest, subcutaneous, etc. Thus, the present device allows the ungulate animal's (e.g. horse, cow, etc.) owner to be alerted on any change in the animal's condition, and thus to provide early therapy, if needed, in order to improve prognosis and reduce healing time. It should be noted that the term "animal" as used in the context of the present invention refers to ungulate mammals, such as horses, cattle, pigs, giraffes, camels, deer and hippos. This early, 24/7, alerting is especially important for ungulate animals and horses in particular which are not under watch / in plain sight of their care takers or owners around the clock, and for prolonged periods, during which an occurrence of the disease or condition can evolve and become irreversible or fatal.

[0033] Accordingly, the present invention aims at developing an apparatus for early detection of inflammatory conditions such as laminitis, and/or other inflammatory conditions and injuries and diseases in an ungulate mammal to enable early treatment and improved prognosis thereof.

[0034] Accordingly, in certain embodiments, the present invention provides a device for early detection of inflammatory conditions or injury and/or for monitoring the recurrence or severity of an inflammation or injury in an ungulate mammal's foot, said
device comprising: (i) at least one sensor 101; (ii) a power source 105; and (iii) a transmitter 104, wherein said device 100 is designed to be placed onto the ungulate mammal's body for continuous monitoring the condition of the ungulate mammal, without disturbing its daily activity. In specific embodiments, the term "ungulate mammal's body" as used herein refers to any location on or in the animal, such as, but not limited to the animal's leg, chest, head, neck, foot, hoof (Fig. IB), rectum, under the skin, internally, or any combination thereof. In certain embodiments, said ungulate mammal is a horse, cattle, pig, deer, camel, etc., and said inflammatory condition is laminitis, tendonitis and/or colic.

[0035] In another specific embodiment, the device 100 of the invention is placed onto the ungulate mammal's foot, hoof, or both, for continuous monitoring the condition of the ungulate mammal's foot, without disturbing its daily activity.

[0036] In certain embodiments, the device of the invention 100 is used for monitoring the animal's physical condition and efforts employed during labor or exercise.

[0037] In certain embodiments, the device 100 of the invention comprises three main components: (i) at least one sensor 101, (ii) a power source 105, such as a battery or a rechargeable battery, and (iii) a transmitter 104 (with or without an antenna). In certain embodiments, the device 100 further comprises (iv) a computer 103 comprising a processor and a memory and/or a display unit. Alternatively, the device 100 of the invention is associated with such a computer 103. After placing the device of the invention 100 on the ungulate mammal's foot (e.g. horse, cow, etc.), the sensor 101 measures specific parameter(s) (e.g. temperature, blood flow, pulse, movement etc.) and transfers the data to the computer 103, which processes the received data and sends an alert through the transmitter 104 to the animal's owner on any "suspected event". In case the computer 103 is not placed within the device 100, the sensor 101 transmits the measured data to the computer 103 through another transmitter 104 located within the device 100. It should be noted that the term "sends an alert" means any suitable way of alert, such as, but not limited to, text message, MMS message, alarm sound, flashing lights, email, etc.

[0038] In certain embodiments, the device 100 of the invention further comprises a buffering module of buffering system, which gathers the data collected from the at least one sensor 101, and transmits said gathered data to the computer 103, either upon demand from the user or at a predetermined time, e.g. when the animal enters the stable, every evening at 19:00, etc.
As used herein, the term "computer" refers to any type of computer that can support the processing of the data, such as, but not limited to, multiple computers, cloud based services, tablet, smartphone, etc.

As used herein, the term "transmitter" refers to any means for transferring data from the sensor 101 to the computer 103, and/or from the computer 103 to a display unit by the user. Non-limiting examples of transmitters include IR signals, Bluetooth, radio signals, etc. Said display unit may be a LCD display, a mobile device 102, light (optionally flashing light) or sound alarm, or any combination thereof.

Under certain adjustments, the device of the invention 100 can be used for monitoring training load, monitoring course of treatment, developing of a smart horse shoe, etc. This is imperative when tracking a horse seeing as the main use of a horse is around its physical activity. The term "smart horse shoe" means any horse shoe which contains the device of the invention, or parts thereof, such as the sensor(s), while other parts are located elsewhere, and enables measuring and/or monitoring several conditions and parameters at the animal's foot, such as pulse, heart rate, blood pressure, temperature, etc.

In certain embodiments, the power source 105 is a rechargeable power source, optionally with a wireless charging capability, such as a rechargeable battery. In a specific embodiment, the recharging of the rechargeable power source 105 is carried out using kinetic charging capabilities, which is a viable option considering the amount of movement and kinetic energy present in the day-to-day activities of the horse's foot.

In certain embodiments, the sensor 101 is either a single designated sensor or an array of sensors each designed to sense a specific feature. Said sensor 101 is designed to monitor at least one of the following parameters: foot temperature, blood flow, and movement inside the horse's foot, the distance between the hoof and bone ("hoof-bone distance"), or any combination thereof.

In certain embodiments, the device 100 of the invention may further comprise a positioning means, such as a GPS, for monitoring location-based information, such as the location of the animal throughout the day, the distances it has passed, its speed of movement, resting periods, etc.

In certain embodiments, the device 100 of the invention may comprise any combination of a variety of different types of sensors, depending, e.g., on the nature of the monitoring application. In this regard, the animal based sensors may be internal (e.g., implantable) or external. Non-limiting examples of animal based sensors that may be
employed include motion/rate sensors, force/strain acoustic sensors, temperature sensors, electrical sensors (e.g., for electrocardiography, pain detection, electrointestineography, etc.), PPG sensors, liquid sensors (e.g., for detecting liquids associated with foaling, or sampling sweat, urine or other liquids), weight sensors, infrared sensors (e.g. for detecting flow or temperature), optical sensors (such as oximeter sensors, motion sensors and cameras, lasers, etc.). Accordingly, in certain embodiments the sensor 101 in the device 100 of the invention is designed to monitor, e.g., in the ungulate mammal's foot, hoof, neck, chest, etc., at least one of: temperature, blood volume, blood flow, pulse/heart rate, pulse wave, bowel sounds and/or activity, movement, $O_2$ saturation in the blood, muscle electrical activity, hoof-bone distance, etc. In certain embodiments, the device of the invention 100 comprises either a single sensor or any combination of sensors for measuring, e.g.: (i) temperature + blood flow; (ii) temperature + pulse; (iii) temperature + $O_2$ saturation in the blood; (iv) blood flow + electricity; (v) hoof-bone distance + pulse; (vi) temperature + $O_2$ saturation in the blood + pulse, or any other combination thereof.

[0046] In specific embodiments, the device 100 of the invention is placed on the ungulate mammal's body by: (i) implantation; (ii) surface attachment; or (iii) fasteners, such as a bracelet, or any combination thereof.

[0047] In other specific embodiments, the device 100 of the invention is placed on the ungulate mammal's foot/hoof by: (i) implantation; (ii) surface attachment; or (iii) fasteners, such as a bracelet, leg warmers, leg wraps, boots etc., or any combination thereof. In a more specific embodiment the device is placed on the ungulate mammal's foot, hoof or both.

[0048] After applying the device 100 of the invention onto the animal's foot, e.g. a horse foot, the sensor 101 (in each of said devices) is first calibrated for a predetermined period of time, e.g. up to a week or longer, e.g. for 15, 30, 45 min, or 1, 1.5, 2, 4, 8, 12, 24, 36, 48 or 72 hours. The data measured separately for each limb, as well as for all 4 limbs together, and is set as the animal's preliminary baseline parameters for future comparisons to the animal's future measured parameters. In order to obtain accurate monitoring, a baseline zone is chosen, so that the data will be synchronized and compared from the exact location in each measurement. In certain embodiments, the baseline is further updated according to data gathered throughout time.

[0049] In certain embodiments, the sensor 101 is a thermal sensor (e.g. a thermistor, a thermocouple, or an infra-red thermometer). In certain embodiments, additional sensors are present in the device of the invention 100, such as accelerometer (for measuring movement),
piezometer (for measuring flow) infrared Doppler (for measuring flow and pulse), etc. In certain embodiments, the device of the invention further comprises a positioning means, such as a GPS.

[0050] In certain embodiments, the device 100 of the invention does not comprise a computer having a processor and a memory, and the transmitter 104 sends the measured data to an exterior computer 103 which calculates and process the received data, and optionally displays the processed data, e.g. through a monitor, and/or sends an alert to the animal's owner, e.g. by text message to the owner's smartphone or to another mobile device.

[0051] Accordingly, in certain embodiments, the present invention provides a system for early detecting, continuously or periodically monitoring and alerting the occurrence, progression and/or the severity of an inflammatory condition or injury in a ungulate mammal's body, said system comprising: (i) the device of the invention 100; (ii) a computer 103 comprising a processor and a memory, coupled to said device 100, adapted to receive data from sensor(s) 101 in said device, and designed to analyze said data; and (iii) an alert module in said computer adapted for producing an alert if said analyzed data is determined to indicate a possible inflammation condition or injury.

[0052] In a specific embodiment, the present invention provides a system for early detecting, continuously or periodically monitoring and alerting the occurrence, progression and/or the severity of an inflammatory condition or injury in a ungulate mammal's foot, said system comprising: (i) the device of the invention 100; (ii) a computer 103 comprising a processor and a memory, coupled to said device 100, adapted to receive data from sensor(s) 101 in said device, and designed to analyze said data; and (iii) an alert module in said computer adapted for producing an alert if said analyzed data is determined to indicate a possible inflammation condition or injury (Fig. 2).

[0053] It should be noted that the term "continuously" as referred to herein throughout the application means constantly or every predetermined period of time, e.g. every 1, 5, 10, 30, 60 min, or every 6, 12, 24, 36, 48, 72 hours, or longer, etc.

[0054] In certain embodiments, the computer 103 is a desktop computer, a laptop computer, a smart phone, a tablet, or any other computer capable of analyzing the data obtained from the sensor(s) 101. In certain embodiments, said computer 103 is connected to all the devices located on a single animal and/or to all the devices located on any number of predetermined animals.
In certain embodiments, the system according to the invention further comprises a transmitter 104 for transmitting alerts, e.g. to the owner's mobile device.

In certain embodiments, the system of the invention is used to monitor an inflammatory condition which is selected from laminitis, tendonitis and colic. In another embodiment, the system is used for monitoring the animal's physical condition and efforts employed during labor or exercise.

In a specific embodiment, the system of the invention comprises 2, 3, 4, 5, 6, 7, 8, 9, 10, or more, devices 100 of the invention, wherein each of said devices is located at a different location on said ungulate mammal's body, while remaining in association with one another and with said computer 103 and alert module.

In certain embodiments, the attachment/detachment mechanism of the device 100 of the invention allows faster placement and removal thereof, or replacement of some of the components in said device, e.g. the sensor 101 and/or the power source 105, without damaging the animal's foot, leg or hoof, and without causing any discomfort thereto.

As mentioned above, the device 100 of the invention will be placed on the ungulate mammal's body according to one of the following 3 options: implantable device; a bracelet or bracelet-like device; or a surface applicator attached, e.g., over the animal's foot or hoof, or any combination therebetween.

It should be noted that the term "foot", "horse foot" or "animal's foot" as used herein refers to any part of the foot or limb, including: hoof, coronet band, distal phalanges, cartilage, sole, etc., and any combination thereof. Accordingly, the clause "on the foot" means placing (the device 100 of the invention) on any part of the foot or on any combination of parts thereof.

Two, non-limiting examples of optional locations for implanting the device of the invention in the animal's foot, are:

- Under the skin, above the coronet band - close to the hoof to feel the temperature and to allow the sensing of the blood flow using a piezosensor.
- Inside the hoof - in the front of the hoof, in a depth that will not reach the lamellas, but will allow for good attachment.

The above implemented device may further comprise external attachment means, such as when the device needs extra securing to the foot.
In certain embodiments, the implemented device of the invention is constructed to be suited for being injected under the skin, for instance just above the hoof without affecting the coronet growth band, or anywhere in the chest and/or belly area.

In certain embodiments, the implemented device of the invention is constructed from a thin cylinder (similar to a nit) with flat "wings" spreading from the sides of the cylinder for implementing inside the hoof. Said wings may comprise cooling means (e.g. micro-fan), or may be designed in a special way (e.g. with large surface area, or with circulating cooling liquid) for cooling the area and/or the device itself. Said "wings" may further assist in attachment of the device 100 to the foot, and may hold the power source 105 and/or transmitting means 104.

Alternatively, said "wings" may be very small in order to reduce possible damage to the foot when the device is installed and/or removed therefrom. Another option is that the "wings" may comprise a mechanism allowing them to open and close therefore assisting in the attachment/detachment of the device of the invention. In certain embodiments, the device 100 of the invention is designed to replace one of the horseshoe nits, thus making the attachment of the device 100 to a part of the regular treatment of the horse.

In certain embodiments, the device 100 of the invention is designed as a bracelet with a single nit or several nits designed to be inserted into or placed onto a single or several different locations on the foot. In this configuration, the nit(s) comprises the sensor(s) 101, such as a thermocouple, and the bracelet may comprise the power source 105, the transmitter 104, and/or the computer 103. This setup is designed for safe and easy placement and removal, with minimal damage to the hoof. Said bracelet provides larger placement area for, e.g., the power source 105 (e.g. battery), antenna (if needed), computer 103, and other sensors, without causing any discomfort to the animal. In certain embodiments, the bracelet further comprises a cooling means.

In certain embodiments, where the device 100 of the invention is implanted in the hoof, the implantation location might be sealed with glue.

In certain embodiments, the device 100 of the invention is designed as a surface attached device containing the power source 105, transmitter 104, and sensor(s) 101 and optionally the computer 103. In this configuration, the device 100 is attached to the surface of the hoof using small nits on several locations and/or glued.

In certain embodiments, the device 100 of the invention is designed as a surface to be placed in an area in the hoof carved specifically to host the device.
Table 1 provides examples of possible setups of the device 100 of the invention:

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<tr>
<th>Advantages</th>
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<tr>
<td>Under the skin implantable device</td>
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<tr>
<td>- Easy attachment</td>
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<tr>
<td>- Does not affect the hoof</td>
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<td>- Location does not change due to hoof growth</td>
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<td>- Soft tissue allows for better signal transfer in the tissue (flow, temp)</td>
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<tr>
<td>Inside the hoof implantable device</td>
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<tr>
<td>- Good attachment</td>
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<td>- Precise location</td>
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<tr>
<td>Nit / Nail / Screw shaped implantable device</td>
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<tr>
<td>- Part of every horse treatment</td>
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<tr>
<td>- Needs to be replaced only as needed (e.g. every 1.5-2 months)</td>
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<tr>
<td>Surface applicator</td>
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<tr>
<td>- Easy to install</td>
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<tr>
<td>- Minimal damage to hoof</td>
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<tr>
<td>- Size can vary</td>
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<tr>
<td>Bracelet</td>
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<td>- Easy to install and secure</td>
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<tr>
<td>- Larger area for power source, transmitter and computer</td>
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In certain embodiments, the present invention provides a method for early detecting the onset of an inflammatory condition or injury in an ungulate mammal, said method comprising: (a) placing or attaching a device of any one of claims 1 to 11 onto at least one location on or in the ungulate mammal's body (such as at least one of its feet/hoofs); (b) monitoring the basal conditions of the ungulate mammal for a predetermined period of time, thereby creating reference conditions; (c) continuously or periodically measuring different parameters in each of the ungulate mammal's monitored locations; (d) continuously or periodically comparing the measured parameters to the reference conditions; (e) continuously or periodically calculating the differences between said measured parameters and reference conditions; (f) determining whether said calculated differences are indicative of occurrence of an inflammatory condition or injury based on various parameters; and (g) presenting the determination and/or the calculated differences and/or alerting the ungulate mammal's owner of the ungulate mammal's condition, wherein said device in step (a) remains on the ungulate mammal's body without disturbing its daily...
activity, thereby enabling early detection of an inflammatory condition or injury for improving prognosis.

[0072] In a specific embodiment, the present invention provides a method for early detecting the onset of an inflammatory condition or injury in an ungulate mammal's foot, said method comprising: (a) placing or attaching a device 100 of the invention onto each or several (i.e. 1-4 legs) of the ungulate mammal's feet/hoofs; (b) monitoring the basal conditions of the ungulate mammal for a predetermined period of time, thereby creating reference conditions; (c) continuously and/or periodically measuring different parameters in each of the ungulate mammal's feet; (d) continuously and/or periodically comparing the measured parameters to the reference conditions; (e) continuously and/or periodically calculating the differences between said measured parameters and reference conditions; (f) determining whether said calculated differences are indicative of occurrence of an inflammatory condition or injury based on any combination of various parameters such as: basal conditions, ambient / environment state (e.g. ambient temperature), latest activity, past diseases or injuries, similar changes in other horses, etc.; and (g) presenting the determination and/or the calculated differences and/or alerting the ungulate mammal's owner of the ungulate mammal's condition, wherein said device in step (a) remains on the ungulate mammal's feet without disturbing the ungulate mammal's daily activity, thereby enabling early detection of an inflammatory condition or injury for improving prognosis.

[0073] In certain embodiments, the above methods further comprise a step (el) of continuously and/or periodically calculating the differences between the measured parameters between all monitored locations of the ungulate mammal, e.g., the limbs. In certain embodiments, the above methods further comprise a step of periodically re-calculating the basal conditions based on the overall gathered data.

[0074] In certain embodiments, the device 100 of the invention remains on the ungulate mammal's body for at least 1 day, 7 days, 1 month, 1 year, or at least 5 years. In certain embodiments, the device 100 of the invention remains on the ungulate mammal's body for any desired period of time, such as 1, 6, 12, 24 hours, or 2, 3, 4, 5, 6 days, or 2 or 3 weeks, or 2, 3, 4, 5, 6, 7, 8, 9, 10 or 11 months.

[0075] In certain embodiments, the present invention further provides a method for continuously monitoring and alerting the occurrence, recurrence and/or severity of laminitis in a horse's foot, said method comprising: (a) placing or attaching a device 100 of the invention onto at least one of the horse's feet/hoofs, or onto all four; (b) monitoring the
current conditions of the horse for a predetermined period of time, thereby creating reference conditions; (c) continuously and/or periodically measuring different parameters in each of the horse's feet; (d) continuously and/or periodically comparing the measured parameters to the reference conditions; (e) continuously and/or periodically calculating the differences between said measured parameters and reference conditions; (f) determining whether said calculated differences are indicative of recurrence of laminitis or whether the laminitis condition is worsen or improves; and (g) presenting said determination of step (f) and/or the calculated differences of step (e) and/or alerting the horse's owner of the horse's condition, wherein said device in step (a) remains on the horse's feet without disturbing the horse's daily activity, thereby enabling continuously monitoring and alerting the recurrence and/or the severity of laminitis for improving prognosis.

[0076] In certain embodiments, the present invention further provides a method for continuously monitoring and alerting the occurrence, recurrence and/or severity of lameness.

[0077] As mentioned throughout the application, the term "predetermined period of time" means any period of time sufficient to determine the animal's basal condition, e.g. while resting, training, competing or working. In certain embodiments, said period of time may be any period in the range of 12 to 72 hours, such as 12, 24, 36, 48, 60 or 72 hours. It certain embodiments, said predetermined period of time may be longer or shorter.

[0078] In certain embodiments, the system of the invention is designed to constantly adjust the basal condition of the tested animal based upon the measured parameters. In such a case, the "predetermined period of time" is indefinite, and the system of the invention constantly updates the basal condition of the animal as it grow, change locations, train, etc.

[0079] In certain embodiments, the present invention provides a device for tracking and monitoring vital signs of an ungulate mammal, said device comprising: (i) at least one sensor 101; (ii) a power source 105; and (iii) a transmitter 104, wherein said device is designed to be placed onto the ungulate mammal's body for continuous monitoring the condition of the ungulate mammal, without disturbing its daily activity.

[0080] In certain embodiments, the condition being monitored by the device of the invention is a disease or injury, such as, but not limited to, laminitis, tendonitis and/or colic.

[0081] In certain embodiments, the device of the invention comprises 2, 3, 4, 5, 6, 7, 8, 9, 10 or more different or same sensors. Said sensors may be located at different locations on the body of said ungulate mammal to be monitored, such as, but not limited to the hoof, leg, back, neck, chest, head, or any combination thereof. In a specific embodiment, at least
one sensor is located inside said ungulate mammal, e.g., in the rectum, subcutaneously, in the colon, etc., or any combination thereof.

[0082] In another specific embodiment, the present invention provides a system for tracking and monitoring vital signs of an ungulate mammal, said system comprising at least one device of the invention.

Treatment of Laminitis

[0083] Acute laminitis constitutes a medical emergency because phalangeal displacement can occur rapidly. Despite prompt therapy, the prognosis is guarded until recovery is complete and it is evident that the hoof architecture is not altered. Most animals should be administered NSAID and other non-inflammatory agents such as lidocaine and dimethyl sulfoxide to reduce the inflammatory process present in the prodromal and acute phases of laminitis. Other options for analgesia include detomidine, butorphanol, morphine, or a constant-rate infusion of a "cocktail" of sedatives and analgesics. In a horse at risk or in the early stages of laminitis, a cryotherapy, where the hoof wall temperature is reduced to a less than 5°C throughout a 48-hour period has been shown to be very effective.

[0084] In addition, during the first 2-3 weeks, the feet should be padded with a soft, resilient substance. Decreasing padding (or beveling the pad) in the region dorsal to the apex of the frog (a V-shaped structure extending forwards across about two-thirds of the sole) decreases the stress on the dorsal laminae. Shoeing horses with laminitis is usually not a good option until about 3 weeks after the onset of laminitis, when the laminar structure may be stabilizing.

[0085] Surgical treatment options include deep digital flexor tenotomy, to neutralize the pull of the deep digital flexor tendon, and dorsal hoof wall resections. Deep digital flexor tenotomy is most commonly performed in cases of chronic rotation that do not respond to the above shoeing techniques; it should always be accompanied by aggressive de-rotation via rasping of the caudal foot. The farrier and veterinarian must address subluxation of the coffin joint subsequent to surgery in the majority of cases. Generally, only a partial hoof wall resection is performed due to the severe digital instability caused by removing the entire dorsal wall.

[0086] As stated above, the most common and straightforward therapy of laminitis is by cryotherapy. There is a multitude of commercially available cryotherapy solutions available today: (i) simple immersion in ice water buckets / tubs; (ii) ice packs; (iii) cold wraps; (iv)
ice boots; (v) bags filled with ice and water; (vi) a combination of pressure and cold applicators such as the Game Ready equine product line.

The above described techniques were previously tested for effectiveness on laminitis showing the following conclusions: cooling up to the level of the fetlock, or a little higher to the mid cannon, is ideal; continuous circulating the coolant in contact with the leg is advantageous; and all techniques are both time-consuming and labor-intensive and require special means to keep the cooling means (e.g. boots or bags) on the limbs of the treated horse.

Accordingly, in certain embodiments, the present invention provides a device 100 for detecting laminitis and/or the onset of laminitis in an angulate mammal, said device further comprises a cooling mechanism for reducing the temperature of the hoof and thereby provide immediate laminitis treatment and reducing healing time.

Examples of such possible cooling mechanism or technology include, but are not limited to, any combination of: (i) fans; (ii) thermoelectric coolers; (iii) heat sinks; and (iv) super cooled/liquid gases. Such a cooling mechanism may further comprise a pump or other circulating means for circulating a coolant therein thereby providing fresh coolant to the point of treatment. Said pump or other circulating means may also be separate from the device 100 and may be connected either directly to the device or assembled separately onto the animal's leg only when needed.

As explained before, the recovery from laminitis is unpredictable, but generally the prognosis is directly proportional to the extent of displacement of the distal phalanx and the resultant lamellar pathology that occurs. Often, if treated promptly using a combination of rational medical therapy and mechanical support, laminitis is controlled and the animal heals. However, horses recovering from even the mildest laminitis should be rested and observed closely to prevent recurrent episodes. Thus, the present invention provides a device 100 for detecting early stages of laminitis or recurrence of laminitis in an angulate mammal, and for providing immediate cryotherapy, optionally in combination with any of drug therapy, compressions, and/or application of pressure, in order to minimize the time between detection of laminitis and beginning of treatment and thereby reducing healing time and improving prognosis.

In certain embodiments, the device 100 of the invention can monitor the efficacy of the treatment procedure, e.g. cryotherapy and/or drug therapy, and support a "closed-loop" process in which it measures the animal's vital signs, determines whether a need exists
for treatment, apply autonomously the required treatment (e.g. according to a predetermined protocol), monitor the efficacy of the treatment and stop or continue treatment accordingly.

[0092] In a specific embodiment, the device 100 of the invention may be associated with an external treatment means, e.g. cooling garment or air conditioning system, and wirelessly activate same.

**The Algorithm**

[0093] The device 100 of the invention transmits the data collected from the sensor(s) 101 to a computer 103 either continuously or at predetermined intervals of time, e.g. every 30 min, every 60 min, every 6 hours, every 12 hours, or every predetermined occasion, e.g. every time the horse passes through the stable door, etc. The first hours after placing the device onto the foot of the animal (e.g. 1, 2, 4, 6, 12, 24, 48, 72 hours), are used to collect data that is used to determine a baseline for the animal's standard physical condition and regular behavior. All the data gathered from this point on, after determining the animal's primary baseline, is compared to this determined baseline, and is used to evaluate the animal's condition, e.g. its health, status (resting/exercising), etc. In certain embodiments, a different baseline is determined for each of the animal's specific activities, e.g. for resting, for running, for training, for competing, for working, etc. In certain embodiments, the baseline is constantly or periodically re-calculated based upon all the parameters gathered up until that re-calculation time, thereby creating an adaptable baseline that is determined according to the animal's age, location, health condition, etc.

[0094] Table 2 below provides examples of possible measured parameters and condition(s) associated therewith:

<table>
<thead>
<tr>
<th>Data</th>
<th>Increase</th>
<th>Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Inflammation event: laminitis, abscess, injuries to tendons, ligaments, etc.</td>
<td>- Inactiveness, possibly due to injury or wound</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Decreased outside temperature</td>
</tr>
<tr>
<td>Blood flow</td>
<td>Exercise, inflammation (including laminitis)</td>
<td>- Inactiveness, possibly due to injury or wound</td>
</tr>
<tr>
<td>Movement</td>
<td>Exercise, itchiness, lameness</td>
<td>- Sleep, pain, lameness</td>
</tr>
<tr>
<td>Hoof-bone distance</td>
<td>Error, osteoporosis, broken leg, cancer, etc.</td>
<td>- Laminitis</td>
</tr>
</tbody>
</table>
Possible algorithms according to the present invention upon detection of any anomaly or possible damage to the animal's, include, but are not limited to, an alert following a sharp temperature elevation or following a temperature elevation for a long period of time compared to the normal elevations measured during the baseline measurements. Another possible example is an alert following a change in movement, such as in lameness, as indicated by an accelerometer or other sensors. In addition, data from all or any combination of the different sensors located onto the animal's body may be compared to provide additional verification. In certain embodiments, the alert contains data regarding the measured difference, e.g. amount of increased temperature and/or the duration of said elevation, the increase in blood flow, the hoof-bone distance, etc. In a specific embodiment, an alert is sent in case of irregular (e.g. increased or decreased) bowl sounds and movements, indicative of digestive system issues such as colic.

In other embodiments, an alert is sent periodically, every predetermined period of time following the first alert to track any changes in the measured condition. In certain embodiments, if no response to the alert is made after, e.g. the 3rd alert, an alert escalation procedure might take place, e.g. by sending another alert to a 2nd contact person. Alternatively, alerts are sent simultaneously to all the designated users, such as the owner, veterinarian, etc. After an alert is received, the user may log on to the system, check the reason for the alert, check for the location of the animal, and silence the system/alert and/or treat the animal if needed. In certain embodiments, the user may activate a cooling mechanism in the device 100 of the invention, if present, thus starting immediately treating the disease or condition. Alternatively, the computer 103 may autonomously activate the cooling mechanism based on predetermined parameters, e.g. at a certain temperature or after a period of time at a certain temperature.

Additional parameters measured by the device 100 of the invention will also be used to monitor the animal's condition as well as to further analyze the reason for the alert generated by one of the measurements. For instance, a rise in temperature will generate an alert, wherein blood flow measurement may indicate that there is (or not) an inflammation; or a sharp hoof-bone distance change may send an alert, that will be evaluated as null due to other measured parameters (GPS, blood flow, temperature, etc.) indicating that the animal is simply training/jumping.
The Alert

[0098] All the data gathered from the sensor(s) 101 in the device 100 of the invention is transferred to a computer 103 having a processor and a memory. The computer 103 continuously monitors the transferred data and compares it to the originally measured baseline and/or analyzes it for anomalies. Any deviation from the regular pattern of the animal's everyday routine would be examined and notified, e.g., immediately or on a daily report that is send to the owner/user, e.g., by email or text message.

[0099] In certain embodiments, several baseline parameters may be determined, e.g. for resting, for training, for competing, etc. In such a case, the system can be calibrated to send alerts according to a specific baseline. Accordingly, when the animal is competing, in which case the overall measured parameters are naturally elevated, no alert will be sent due to using the "resting baseline". Only if the measured parameters exceed those of the "competing baseline" an alert will be sent.

[0100] In certain embodiment, the alert is sent by any means selected by the user, such as by email, phone call, and text message, or any combination thereof. The user may also determine for which event an alert should be sent. For instance, temperature elevation of a certain degree, decreased movement, decreased bone-hoof distance, etc., and any combination thereof.

[0101] The invention will now be illustrated by the following non-limiting examples.

EXEMPLARY

Example 1

Preclinical trials for the development and design of the device

[0102] During the developmental phase of the device several parameters will be evaluated, so that the design of the device will allow for the most accurate data possible with minimal pain to the horse along with the easiest attaching mechanism and longest attachment period. At different stages of the development, different models would be used to measure parameters such as hoof dimensions, temperatures distributions and fluctuations, flow in the arteries and veins, etc.:

1. Healthy horse;
2. A horse that suffer from laminitis or acute laminitis; and
3. A horse that recovered from acute laminitis (after the first episode, horses are prone to suffer from recurrence episodes of laminitis, thus can serve as a good prediction model).
Sensor location and sensitivity

[00103] Accurate temperature measurement on and/or in the surface of the hoof as well as on the skin will provide evidence for the best location of the sensor. It is important to monitor healthy horses as well as horses with laminitis (preferably acute). In addition, horses after surgery or sepsis are of higher risk for developing laminitis, and thus can also serve to identify the most accurate location for placing the temperature sensor.

Flow sensor location and sensitivity

[00104] For optimized blood flow measurement, readings from different locations of the piezo sensor would be taken using a measuring sensor tapped/attached to the skin of a healthy horse. A short training session of a horse can provide the evidence of the sensitivity of the sensor and the preferable location of the sensor.

Sensor attachment

[00105] When the sensor will be attached to the exterior section of the foot or implanted therein, the attachment/detachment mechanism, as well as the stability of the sensor, will need to be examined. In order to do this, a synthetic model of the horse's foot can be manufactured. Nevertheless, the process would be followed by attaching the sensor to the horse's foot. This should be done following the evaluation of a veterinary that the process would not affect the hoof. The sensor would be attached to one leg (preferably one of the front limbs) and the sensor location, stability and accuracy would be monitored closely.

Example 2
Animal trials

Objectives

[00106] The objective of the clinical trial is to assess the safety and efficacy of the device. Thus, the end points of the clinical trial will have to answer the following questions:
1. Device safety - no long term damage to the horse's hoof, as well as no visible signs of discomfort of the horse;
2. Long term accuracy of the data (temperature, blood flow, pulse, and any other measurements);
3. Effect of outside effects on the sensor's sensitivity and accuracy (such as outside temperature, wind, motion, etc.);
4. The baseline definition for the monitoring algorithm;
5. Device temperature - whether cooling the device is needed or not.
Protocol/Methods

The device 100 of the invention will be attached to the horse's body, preferably to its legs. During the first 48-72 hours the horse would be kept in a close place (stable) and monitored for its different parameters, such as hoof temperature, behavior, pain, blood flow, and movement, at least 4 times a day with known devices. Following this, the horse will be returned to its normal surroundings and everyday routine for another 2-4 weeks, during which, the horse will be monitored at least twice a day for the temperature of the hoofs, blood flow, movement, pain, etc. using standard measuring apparatuses. During this period of time, the horse owner will place cold bandages or hot straps of clothes to check the accuracy of the data as well as work the horse (practices and rides) and will monitor the horse's parameters throughout each of these events.

After a period of 30 days with the device 100 of the invention, physical examination and an X-ray radiograph of the foot would be made, to check for any abnormalities that might have developed in the horse's hoofs.

Data obtained by sensors in the device of the invention would be monitored with regard to a predefined normal baseline behavior, such as regular duration of temperature elevation, the effect of different temperatures throughout the day and according to the horse's routine, the effect of outside temperature application, the effect of a long ride, etc.

After the 30 days, the device will remain on the horse's foot to evaluate the stability of the device on a horse's foot during its everyday routine, as well as to determine how long the device remains accurate, with regard to the changed location of the device due to the growth of the hoof. Long term effects of the device on the horse's foot would be considered once a month through physical examination of the hoof by an expert.

Expected Results

The results expected from this trial are quite straightforward:

1) The device is designed to minimize any effect (if exists) to the animal's foot, and thus would be safe for use on animals, such as horses;

2) Continuous data regarding the temperature of the hoof (flow in the hoof and the amount of movement of the limb). This will allow for the construction of an algorithm that defines what is "healthy data" and "normal baseline" per animal.

3) Outside changes, such as surrounding temperature, wind, etc., should not affect the analyzed data. This is since such changes are different from those occurring during an
inflammatory event or other injuries (e.g. longer period of time of heat elevation/cooling, etc.) and thus the system of the invention would be able to detect their causes and distinguish such changes from actual measurements.

4) Comparison of this data with the outside collected data will provide the accuracy of the data - which is expected to be high in the first few months, with a reduced accuracy over time due to the change in the device's location caused by the hoofs growth.

5) Stability of the device 100 - the design of the device provides a stable device that enables it to remain in its location until its removal.

**Example 3**

**Temperature test**

[00112] In order to measure the horse's temperature the following procedure was performed, either with a raspberry-pi & phidgets setup for PoC experiments, or with MLX90614 IR sensor & 10k thermistor:

1. fixing the raspberry-pi and battery pack on the lower part of the horse's leg in several different locations;
2. fixing the phidget (module 1048 with k type thermistors) under the raspberry-pi and the thermistor heads to the hoof wall in two locations;
3. connecting the device to a Wi-Fi network;
4. collecting and aggregating data from the device, including ambient temperature;
5. tracking the data while standing for a few minutes; and
6. tracking the data while trotting and running for a few minutes.

[00113] Figs. 3A-3C summarize the results obtained from one leg of an exemplary horse: Fig. 3A shows results obtained when using the raspberry-pi & phidgets setup, and Figs. 3B and 3C show results obtained when using the MLX90614 IR sensor & 10k thermistor.

[00114] The results demonstrate that there is a difference between different feet and slight differences between different locations on the same leg.

**Example 4**

**Algorithm of online service**

[00115] Fig. 4 illustrates one possible way of how the online service according to the present invention works: a stream of vital signs from the devices attached to the animal is transmitted to the online system for analysis. The various vital signs will first be analyzed to
ascertain each specific horse and limb baseline characteristics for specific parts of the day (e.g. day vs. night time activity), week (e.g. work days vs. weekends), and year (e.g. summer vs. winter ambient temperature affects).

[00116] These baselines characteristics will also be continuously re-calculated to account for subtle changes which occur due to aging and the horse's changing surroundings and routine.

[00117] Once ascertained, anomalies from the norm will be captured and further analyzed to filter out the effects of ambient factors. The following are some, but not all, such factors which are taken into consideration:

- A horse in transit (detected via GPS and motion sensors) increasing anxiety;
- A horse which is not in its normal surroundings, spurring recalculation of ambient factors;
- Unusually warm / cold weather;
- Stepping in something colder / warmer than usual;
- Prolonged activity times; and
- Being left out in the sun / specific limbs in direct sun light.

[00118] Table 3 below provides examples of measured data and its possible causes:

<table>
<thead>
<tr>
<th>Data</th>
<th>Increase</th>
<th>Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Inflammation event – due to e.g. laminitis, abscess injuries to tendons and ligaments or any other inflammatory process, e.g., in the hoof; or injuries such as nails or improper shoeing.</td>
<td>Horse not active, possibly wounded; Decreased outside temperature</td>
</tr>
<tr>
<td>Blood flow</td>
<td>Exercise, inflammatory event including laminitis or injury such as a nail or improper shoeing</td>
<td>Horse not active, possibly wounded</td>
</tr>
<tr>
<td>Movement</td>
<td>Exercise, itchiness</td>
<td>Sleep, pain, lameness</td>
</tr>
</tbody>
</table>

[00119] The algorithm according to the invention will look for any deviation from the norm, following factorization of external influences. Deviations will be categorized by their severity and an appropriate alert will be sent, e.g., to the horse's owner, or proper measures will be taken, e.g. beginning of treatment (optionally autonomously by the device 100).
The following are examples of main possible anomalies and their severity / escalation:

- **Low:**
  - Momentary (up to an hour) lameness over the course of a day;
  - Lameness in a specific leg;
  - Temporarily (a few hours) increased temperatures;
  - Temporarily (a few hours) increased pulse;
  - Lowered activity during a typical work day; and
  - Abnormal amounts of laying.

- **High:**
  - Lameness accompanied by abnormal hoof wall temperature;
  - Abnormally lowered activity off work hours accompanied by increased pulse;
  - Lameness of a single foot accompanied by increased temperatures in that specific foot;
  - A prolonged (more than 2 days) period of abnormal laying.

- **Critical:**
  - Prolonged (more than 3 hours) abnormal hoof wall temperature accompanied by a bounding pulse;
  - Abnormal temperatures and pulse in both front feet; and
  - Prolonged (more than 30 minutes) thrashing or rolling.

**Alert**

According to the algorithm of the invention, anomalies categorized into their respective severities will be sent as an alert to the required individual(s). All alerts will be stored and viewable as a part of the animal's medical history files on the system. This will aid in better analyzing recurrence and the signs before the onset or reassurance of various diseases including laminitis.

In certain embodiments, low level alerts will be sent as emails to the animal owner / caretaker for future follow-up. These are seen mostly as general signs of momentary issues and are partially to allow the owner / caretaker to better understand their animal's behavior and stay in contact with them.

In other embodiments, high level alerts will be sent to the owner / caretaker on their app and / or as a text message for immediate review. These are most probably health
incidents which will greatly benefit from swift application of remedies or change in the animal's routine.

[00124] In yet other embodiments, critical level alerts will be sent to the owner / caretaker on their app and / or as a text message as well as to their on-call / designated vet for immediate review. These are categorized as high risk, high impact, potentially fatal incidents which will greatly benefit from immediate veterinary attention.

[00125] In specific embodiments, unanswered / unapproved alerts will go through a pre-defined escalation path (from owner / veterinarian to their next person in charge) in case of owner unavailability.

[00126] In another specific embodiment, following the alerts, or alongside it, a treatment protocol is commenced.

Reference list

- Worster et al., New Zealand Veterinary Journal, 48, 111-116, 2000;
- Buchner and Wiesenhofer, Pferdeheilkunde, 27, 670-673, 2011;
CLAIMS

1. A device for early detection of inflammatory conditions or injury and/or for monitoring the recurrence or severity of an inflammation or injury in an ungulate mammal, said device comprising:
   - at least one sensor;
   - a power source; and
   - a transmitter,

   wherein said device is designed to be placed onto the ungulate mammal's body for continuous monitoring the condition of the ungulate mammal, without disturbing its daily activity.

2. The device of claim 1, wherein said ungulate mammal is a horse, cattle, pig, deer, or camel, etc.

3. The device of claim 1 or 2, wherein said device is placed onto the ungulate mammal's leg, foot, hoof, neck, chest, belly, or any combination thereof, for continuous monitoring the health condition(s) of the ungulate mammal, without disturbing its daily activity.

4. The device of any one of claims 1-3, wherein said inflammatory condition is selected from laminitis, tendonitis and colic.

5. The device of any one of claims 1-3, which is used for monitoring the animal's physical condition during resting and during efforts employed in labor or exercise.

6. The device of any one of claims 1 to 5, further comprising a computer having a processor and a memory, and/or a display unit.

7. The device of any one of claims 1 to 6, wherein said power source is a rechargeable power source, optionally with a wireless charging capability, such as a rechargeable battery.

8. The device of any one of claims 1 to 7, wherein the device is placed on the ungulate mammal's foot/hoof/limb by: (i) implantation; (ii) surface attachment; or (iii) fasteners, such as a bracelet, leg warmers, leg wraps, boots etc., or any combination thereof.

9. The device of any one of the preceding claims, wherein said at least one sensor is designed to monitor at least one of: temperature, blood volume, blood flow, pulse/heart rate,
pulse wave, bowl sounds and/or activity, movement, $O_2$ saturation in the blood, muscle electrical activity, hoof-bone distance, etc.

10. The device of any one of the preceding claims, further comprising a global positioning system (GPS).

11. A system for early detecting, continuously or periodically monitoring and alerting the occurrence, progression and/or the severity of laminitis or any other inflammatory condition or injury in a ungulate mammal's body, said system comprising:
   - the device of any one of claims 1 to 10;
   - a computer comprising a processor and a memory, coupled to said device, adapted to receive data from sensor(s) in said device, and designed to analyze said data; and
   - an alert module in said computer adapted for producing an alert if said analyzed data is determined to indicate laminitis or a possible inflammation condition or injury.

12. The system of claim 11, wherein said computer is a desktop computer, a laptop computer, a smart phone, a tablet, or any other computer- local, remote, or in the cloud.

13. The system according to claim 11 or 12, further comprising a transmitter for transmitting alerts.

14. The system of any one of claims 11 to 13, wherein said computer is connected to all the devices located on a single animal.

15. The system of any one of claims 11 to 13, wherein said computer is connected to all the devices located on any number of predetermined animals.

16. The system according to any one of claims 11 to 15, wherein said ungulate mammal is a horse, cattle, pig, deer, or camel, etc.

17. The system of any one of claims 11 to 16, wherein said inflammatory condition is selected from laminitis, tendonitis and colic.

18. The system of any one of claims 11 to 17, which is used for monitoring the animal's physical condition and efforts employed during labor or exercise.
19. The system of any one of claims 11 to 18, comprising 2, 3, 4, 5, 6, 7, 8, 9 or 10 devices according to claims 1 to 10, wherein each of said devices is located at a different location on said ungulate mammal's body, while remaining in association with one another and with said computer and alert module.

20. A method for early detecting the onset of laminitis or any inflammatory condition or injury in an ungulate mammal, said method comprising:
   (a) placing or attaching a device of any one of claims 1 to 11 onto at least one location on or in the ungulate mammal's body;
   (b) monitoring the basal conditions of the ungulate mammal for a predetermined period of time, thereby creating reference conditions;
   (c) continuously or periodically measuring different parameters in each of the ungulate mammal's monitored locations;
   (d) continuously or periodically comparing the measured parameters to the reference conditions;
   (e) continuously or periodically calculating the differences between said measured parameters and reference conditions;
   (f) determining whether said calculated differences are indicative of occurrence of an inflammatory condition or injury based on various parameters; and
   (g) presenting the determination and/or the calculated differences and/or alerting the ungulate mammal's owner of the ungulate mammal's condition,

wherein said device in step (a) remains on the ungulate mammal's body without disturbing its daily activity, thereby enabling early detection of an inflammatory condition or injury for improving prognosis.

21. The method of claim 20, further comprising a step (el) of continuously and/or periodically calculating the differences between the measured parameters between all monitored locations of the ungulate mammal.

22. The method of claim 20 or 21, further comprising a step of periodically re-calculating the basal conditions based on the overall gathered data.

23. The method of any one of claims 20 to 22, wherein said device of (a) remains on the ungulate mammal's body for at least 1 day, 7 days, 1 month, 1 year, or at least 5 years.
24. The method of any one of claims 20 to 23, wherein ungulate mammal is a horse, cattle, pig, deer, or camel, etc.

25. The method of any one of claims 20 to 24, wherein said inflammatory condition is selected from: laminitis, tendonitis and colic.

26. A method for continuously monitoring and alerting the occurrence, recurrence and/or severity of laminitis in a horse's foot, said method comprising:
   (a) placing or attaching a device of any one of claims 1 to 10 onto each of the horse's four feet/hoofs;
   (b) monitoring the current conditions of the horse for a predetermined period of time, thereby creating reference conditions;
   (c) continuously and/or periodically measuring different parameters in each of the horse's monitored feet;
   (d) continuously and/or periodically comparing the measured parameters to the reference conditions;
   (e) continuously and/or periodically calculating the differences between said measured parameters and reference conditions;
   (f) determining whether said calculated differences are indicative of recurrence of laminitis or whether the laminitis condition is worsen or improving; and
   (g) presenting said determination of step (f) and/or the calculated differences of step (e) and/or alerting the horse's owner of the horse's condition,
   wherein said device in step (a) remains on the horse's feet without disturbing the horse's daily activity, thereby enabling continuously monitoring and alerting the recurrence and/or the severity of laminitis for improving prognosis.

27. The method of claim 20 or 26, wherein said predetermined period of time in step (b) is between 12 to 72 hours.

28. The method of claim 20 or 26, wherein the device of (a) is placed onto the animal's foot, hoof or both.
29. The method of claim 28, wherein the device is placed by (i) implantation; (ii) surface attachment; or (iii) fasteners, such as a bracelet, leg warmers, leg wraps, boots etc., or any combination thereof.

30. A device for tracking and monitoring vital signs of an ungulate mammal, said device comprising:
   - at least one sensor;
   - a power source; and
   - a transmitter,

   wherein said device is designed to be placed onto the ungulate mammal's body for continuous monitoring the condition of the ungulate mammal, without disturbing its daily activity.

31. The device of claim 30, wherein said condition being monitored is a disease or injury.

32. The device of claim 31, wherein said disease is laminitis, tendonitis and/or colic.

33. The device of any one of claims 30-32, wherein said device comprises 2, 3, 4, 5, 6, 7, 8, 9, or 10 different or same sensors.

34. The device of claim 33, wherein said sensors are located at different locations on the body of said ungulate mammal.

35. The device of claim 34, wherein at least one sensor is located inside said ungulate mammal.

36. The device of any one of claims 30 to 35, wherein the device is placed on the ungulate mammal's body by: (i) implantation; (ii) surface attachment; or (iii) fasteners, or any combination thereof.

37. A system for tracking and monitoring vital signs of an ungulate mammal, said system comprising at least one device of any one of claims 30-36.
Temperature by Minute

Fig. 3B
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC (2016.01) A61B 5/00, A61B 5/02, A61B 5/103
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)
IPC (2016.01) A61B 5/00, A61B 5/02, A61B 5/103
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of data base and, where practicable, search terms used)
Databases consulted: Esp@cenet, Google Patents, Google Scholar, FamPat database
Search terms used: wearable device, detect, monitor, injury, inflammation, temperature, laminitis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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