

A DEVICE FOR REGULATING A PHYSIOLOGICAL TEMPERATURE AND METHODS OF USE THEREOF

5 FIELD OF THE INVENTION

The present invention relates to a device and methods for regulating the temperature of the genital area of a male or female subject. In particularly preferred embodiments, a device as described herein has application to regulating the temperature of the testes of a male subject for improving fertility and/or other fertility related physiological outcomes of the subject.

BACKGROUND TO THE INVENTION

15 It is common for a batsman or batter to wear genital protectors in their underwear for protection of the genital area when playing cricket or baseball to minimise the risk of injury that may arise from being struck in that region by the playing ball. Hockey players can also wear such protectors to reduce the risk of injury if struck by the hockey ball or puck, particularly in the case of ice hockey. Such protectors typically comprise a stiff plastic cup (which in the case of cricket is also known as a "box"), that is located to cover the genitals. However, the wearing of the cup can be uncomfortable due to the accumulation of heat in the genital area. This is particularly the case for a cricket batsman who may be at the cricket pitch for long hours at a time on hot days.

25 For males, elevated temperature of the genital area and specifically the testes can be associated with reduced fertility. More specifically, the temperature of the testes is normally less than that of core body temperature and elevated temperature of the testes can adversely impact on fertility. For instance, semen parameters which can include but not restricted to sperm count, can be decreased. Normal sperm development may also be adversely affected resulting in aberrant sperm morphology and/or sperm motility. Both testicular germ cells and epididymal sperm and are sensitive to elevated temperature of the testes as may arise from testicular hyperthermia

or acute rises in ambient temperature of the genital area. Besides impaired progressive sperm motility elevated temperature effects can also adversely impact on sperm viability, cell concentration, semen volume, and semen pH. Further, sperm DNA fragmentation and/or DNA damage can arise or be increased with scrotal hyperthermia.

- 5 Taken as a whole, elevated testicular temperature can significantly adversely impact sperm function and ability to fertilise, and also on semen quality.

For natural regulation of temperature, the positions of the testes of the human male are offset relative to one another, with the left testicle normally being suspended located lower than the other in the scrotum. However, this natural regulation of the
10 temperature of the testes can be impaired by exposure to heat or hot climate or when playing sports such as cricket, baseball or hockey as described above, the wearing of tight-fitting underwear, sitting at desks for long hours as is common in modern day workplaces or whilst driving or operating vehicles, as well as obesity, and potentially even sedentary lifestyles. Elevated temperature of the testes adversely impacting on
15 male fertility can also come about as a result of varicocele, a testicular pathology in which blood pools in enlarged veins of the scrotum. Cryptorchidism where the testis do not descend, can also cause elevated testicular temperature. For some men, elevated testicular temperatures arise that are idiopathic in nature, and have no identified associated pathology.

20 Chilled packs, for instance, have been used to treat or ameliorate the adverse effects of elevated testicular temperature on male fertility. For example, a device marketed under the brand name UNDERDOG™ (Underdog Fertility, Orangeville, ON, Canada) has previously been provided that comprises a contoured wedge-shaped ice pack inserted into a soft sleeve. To use the device, the chilled ice pack is inserted in the
25 sleeve and is slid between the legs of the subject while the subject is in a seated position whereby the device is located under the subject's testes and the cooling of the testes is achieved through the trousers of the subject whilst the subject remains in the seated position. Another known system marketed under the brand name SNOWBALLS™ (Under Ice LLC, Richmond, VA, USA). This system entails inserting chilled/ice
30 pack(s) into a pouch provided in underwear worn by the subject such that the ice packs are located for cooling of the subject's testes. However, such systems suffer from the significant disadvantage of the cooling effect being dependent on the chilled packs

remaining cool and so their use is limited by the length of time the packs remain cool. Additionally, the cooling of the testes is directly dependent on heat transfer through the clothing of the subject with the potential for significant discomfort arising from overcooling. Furthermore, there is no temperature control for such devices.

5 Another system marketed under the brand name CoolMenTM (Cooltec Sp. Z o.o, Wroclaw, Poland) is a lightweight device used to boost sperm production. The use of this device requires the user to place a cup around the scrotum. A battery powered Peltier cooler system is then used to cool the environment around scrotum. Peltier devices though generate heat which must be removed away from the scrotal area.

10 An improved device for controlling the temperature of the genital area of males and females or at least the provision of an alternative device for this purpose is desirable.

SUMMARY OF THE INVENTION

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Broadly, the present invention relates to a device for regulating the temperature of a genital area of a male or female subject.

20 More particularly, in one aspect of the present invention there is provided a wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:

an air delivery portion configured for being fitted about the genital area; and
at least one electrically powered fan arranged for flowing air to the air delivery portion for contact of the air with the genital area to cool the genital area with operation of the fan.

25 Typically, the at least one fan is arranged for flowing the air to the genital area of the subject from externally of an undergarment in which the cooling device is worn by the subject in use of the device.

Typically, the cooling device comprises ducting for directing the air flow to the genital area.

30 In another aspect the present invention relates to a wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:

ducting for directing air flow to the genital area;
at least one electrically powered fan arranged for flowing the air along the
ducting into contact with the genital area with operation of the fan; and
a control system operable to control the operation of the fan.

5 Typically, in embodiments described herein the ducting directs the air flow from the fans to the delivery portion, the ducting opening into the air delivery portion for the flow of the air into contact with the genital area.

Typically, the cooling device will further comprise at least one temperature sensor for measuring temperature of, or in proximity to, the genital area.

10 Typically, the control system of the device is operable to control the operation of the fan in response to the temperature measured by the at least one temperature sensor.

Accordingly, another aspect of the invention relates to a wearable cooling device for regulating the temperature of an external genital area of a subject, the device
15 comprising:

ducting for flowing air to the genital area;
at least one electrically powered fan arranged for flowing the air along the
ducting into contact with the genital area with operation of the fan;
at least one temperature sensor for measuring temperature of, or in proximity to,

20 the genital area; and

a control system operable to control the operation of the fan in response to the temperature measured by the at least one temperature sensor.

Typically, the control system is operable to control the operation of the fan to inhibit the measured temperature from increasing or to cool the genital area.

25 Typically, the at least one fan is operated to lower the temperature of the genital area and most preferably, to lower the temperature of the genital area to a predetermined temperature.

In particularly preferred embodiments, the at least one fan is operated to maintain the temperature of the genital area at the predetermined temperature.

30 In embodiments described herein, the air flow to the genital area of the subject effects evaporative cooling of the genital area and/or or heat transfer from the genital area.

In at least some embodiments, the at least one fan is located in the ducting to direct the flow of air along the ducting to the genital area although the fan(s) may be arranged in any suitable manner for achieving the flow of the air to the genital area via the ducting. In other embodiments, the at least one fan is mounted externally of the ducting for flowing the air through the ducting to the air delivery portion for contact with the genital area.

In particularly preferred embodiments, the device is configured to draw air from above trouser height of the subject for flow of the air to the air delivery portion with the operation of the fan(s). Typically, in these embodiments, the ducting opens at or above trouser height for flow of the air into the ducting.

In other embodiments, the device is configured to draw the air at groin height of the subject external to an undergarment worn by the subject, for flow of the air to the air delivery portion with the operation of the fan(s). Typically, in these embodiments, the ducting is arranged for flow of the air into the ducting at the groin height.

In particularly preferred embodiments, the air delivery portion is configured for being fitted over the genital area.

Most typically, the air delivery portion is shaped to cup the genital area of the when the device is worn by the subject.

Typically, in embodiments provided with at least one temperature sensor as described above, the temperature sensor is mounted on the air delivery portion to face toward the genital area for measurement of the temperature.

In yet another aspect of the invention there is provided a wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:

at least one electrically powered fan arranged for flowing air into contact with the genital area with operation of the fan;

at least one temperature sensor for measuring temperature of, or in proximity to, the genital area; and

a control system operable to control the operation of the fan in response to the temperature of the measured by the temperature sensor.

In another aspect of the invention there is provided a wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:

- an air delivery portion for being fitted about the genital area for delivery of air
- 5 into contact with the genital area;
- at least one electrically powered fan arranged for flowing the air to the air delivery portion with operation of the fan; and
- a control system operable to control the operation of the fan.

Typically, the at least one fan is operable to start or increase the flow of air to

10 the genital area when the measured temperature is above a predetermined temperature and to reduce or stop the flow of air to the genital area as the measured temperature decreases, or the measured temperature approaches, reaches or falls below the predetermined temperature.

In particularly preferred embodiments, the device comprises a plurality of said

15 temperature sensors and the fan is operable to start or increase the flow of air to the genital area when the temperature measured by at least one of the sensors is above a predetermined temperature and to reduce or stop the flow of air to the genital area as the temperature measured by at least one of the sensors decreases, or the measured temperature approaches, reaches or falls below the predetermined temperature.

20 In embodiments, the starting, stopping, increase and/or decrease of the air flow to the genital area may be controlled by the temperature measured by the same one of temperature sensors or by different ones of the temperature sensors.

Embodiments of a cooling device in accordance with the present invention may also comprise a humidity sensor for measurement of humidity in proximity to the

25 genital area. As described herein, the measured humidity can be utilised to provide data for assessment of heat stress and related operation of the fan(s) of the cooling device.

Typically, in embodiments comprising a humidity sensor, the at least one fan is operable to start or increase the flow of air to the genital area when the temperature

30 measured by the at least one temperature sensor is above a predetermined temperature, and the speed of the fan is controlled by the control system of the device to correlate

with the humidity or humidity level measured in proximity to the genital area by the humidity sensor.

Typically, the device comprises a plurality of fans for flowing the air to the genital area of the subject.

- 5 The ducting of embodiments as described herein can comprise first and second ducts for directing the flow of air to the genital area. In at least some embodiments, the first and second ducts are arranged at an angle so that the ducts converge toward one another in a direction toward the genital area when the device is worn by the subject, and each of the first and second ducts is arranged to flow air to the genital area under
10 the action of the at least one fan. In such embodiments, the device can comprise a respective fan arranged for flowing the air to the genital area through a corresponding one of the ducts.

- The temperature measured by the at least one temperature sensor in at least some embodiments in accordance with the present disclosure can be the surface
15 temperature of the genital area. In such embodiments, the, or each temperature sensor is typically respectively an infrared temperature sensor. Most typically, in these embodiments, the at least one temperature sensor is arranged to measure the temperature at or about a mid-region of the genital area in a top to bottom direction of the genital area.

- 20 In other embodiments and as described above, the temperature sensor(s) can be for measuring temperature in proximity to the genital area. Sensors which may be utilised for this purpose include environmental sensors which comprise both the temperature sensor and a humidity sensor as described above.

- Still further, a cooling device embodied by the invention may comprise at least
25 one further temperature sensor for measuring temperature of the genital area, e.g., an ambient or a surface temperature. In embodiments provided with a further such temperature sensor, the temperature measured by the further sensor may be used as a reference temperature for controlling operation of the fan(s) and/or as a fail-safe temperature measurement for continued operation of the cooling device in the event the
30 above-described primary (e.g., infrared) or other temperature sensor(s) or circuitry associated therewith fail(s). The further temperature sensor can be provided for measuring temperature when placed in contact with, or in proximity to, the genital area

such as e.g., the neck of the scrotum of a male subject. The further temperature sensor can be, for example, a thermistor, infrared or other temperature sensitive sensor.

Typically, when the subject is a male, the genital area is the scrotum of the subject.

5 Most typically in such embodiments, the device is configured for regulating the temperature of the testes of the male subject by effecting cooling of the surface of the scrotum of the subject.

 Hence, another aspect the invention relates to a wearable cooling device for regulating the temperature of the testes of a male subject, the device comprising ducting
10 for directing air flow to the scrotum of the subject, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the subject's scrotum with operation of the fan, at least one temperature sensor for measuring temperature of, or in proximity to, the scrotum, and a control system operable to control the operation of the fan in response to the temperature of the surface of the scrotum measured by the
15 at least one temperature sensor.

 A cooling device in accordance with the invention may also further comprise a power source for providing electrical power for operation the device. Alternatively, the device may be connectable to an external power source for operation the device. The power source can for instance be or comprise a rechargeable battery.

20 Whether a device as described herein is for being worn by a male or female, the predetermined temperature will generally be a temperature that is comfortable for the subject. Typically, in the case of a male, the predetermined temperature is a temperature for reducing and/or maintaining the temperature of the testes to below the core body temperature of the subject.

25 In embodiments described herein, the predetermined temperature can comprise a temperature within a predetermined temperature range. In the case of male subjects, this can be a temperature range of from about 29°C or less up to about 34 °C or 35 °C, inclusive.

 In another aspect of the invention there is provided a method for cooling the
30 temperature of an external genital area of a subject, comprising:

 providing a wearable cooling device for being worn by the subject to cool the genital area, the cooling device comprising an air delivery portion for being fitted about

the genital area for delivery of air flow into contact with the genital area, at least one electrically powered fan arranged for flowing the ambient air to the air delivery portion with operation of the fan, and a control system operable to control the operation of the fan;

- 5 fitting the device to the subject; and
 operating the control system of the device for operation of the fan to flow the air to the air delivery portion while the device is worn by the subject.

In another aspect of the invention there is provided a method for cooling an external genital area of a subject, comprising:

- 10 providing a wearable cooling device for being worn by the subject to cool the genital area, the cooling device comprising ducting for directing air flow to the genital area, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the genital area with operation of the fan, and a control system operable to control the operation of the fan;

- 15 fitting the device to the subject; and
 operating the control system of the device for operation of the fan to flow the air to the genital area while the device is worn by the subject.

In another aspect of the invention there is provided a method for regulating the temperature of an external genital area of a subject, comprising:

- 20 providing a wearable cooling device for being worn by the subject to cool the genital area, the cooling device comprising ducting for directing air flow to the genital area, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the genital area with operation of the fan, at least one temperature sensor for measuring the temperature of, or in proximity to, the genital area, and a
25 control system operable to control the operation of the fan;

- fitting the device to the subject; and
 operating the control system of the device to control the operation of the fan in response to the temperature measured by the at least one temperature sensor, while the device is worn by the subject.

- 30 In another aspect of the invention there is provided a method for regulating the temperature of an external genital area of a subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the genital area of the subject, the cooling device comprising at least one electrically powered fan arranged for flowing air into contact with the genital area with operation of the fan, at least one temperature sensor for measuring temperature of the genital area, and a control system operable to control the operation of the fan in response to the temperature of the genital area measured by the temperature sensor;

fitting the device to the subject; and

operating the control system of the device to control the operation of the fan in response to the temperature of the surface of the genital area measured by the at least one temperature sensor, while the device is worn by the subject.

In another aspect of the invention there is provided a method for regulating the temperature of the testes of a male subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the surface temperature of the scrotum of the subject, the cooling device comprising ducting for directing air flow to the scrotum, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the subject's scrotum with operation of the fan, at least one temperature sensor for measuring the surface temperature of the scrotum, and a control system operable to control the operation of the fan;

fitting the device to the subject; and

operating the control system of the device to control the operation of the fan in response to the temperature of the surface of the scrotum measured by the at least one temperature sensor, while the device is worn by the subject.

In still another aspect of the invention there is provided a method for regulating the temperature of the testes of a male subject, comprising:

fitting a wearable device to the subject for cooling the surface temperature of the scrotum of the subject, the cooling device comprising ducting for directing the ambient air to the scrotum, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the subject's scrotum with operation of the fan, at least one temperature sensor for measuring the surface temperature of the scrotum, and a control system operable to control the operation of the fan; and

operating the control system of the device to control the operation of the fan in response to the temperature of the surface of the scrotum measured by the at least one temperature sensor, while the device is worn by the subject.

To facilitate the wearing of a device in accordance with the present disclosure
5 by sports people whilst playing their chosen sport such as cricket, baseball, field or ice hockey, or any other sport in which the genital area may be at risk of contact injury, a device as described herein may incorporate the genital protector. In this instance, the ducting of the device may open into the genital protector and when provided, the at least one temperature sensor of the device can be located for measuring the temperature
10 of, or proximal to, the genital area under the genital protector. Alternatively, for instance, in at least some embodiments, the air delivery portion of the device can be configured and dimensioned as necessary to act as the genital protector to protect the subject against impact injury to the genital area.

In one form of a cooling device as described herein the fan may be configured
15 for operation to provide for comfort of the subject without any monitoring of the temperature of the genital area. Indeed, in embodiments of the cooling device in accordance with the present disclosure, the device may not be provided with any temperature sensors for measuring temperature of, or in proximity to, the genital area, and the control system of such embodiments may comprise or consist of an on/off
20 switch provided on the device itself for manually turning the fan on or off as desired by the user.

In other embodiments, the operation of a cooling device in accordance with the invention may be achieved via the use of a software application (app) installed on a smartphone, tablet, computer or other suitable electronic device via wireless
25 connectivity with the cooling device. In embodiments, the app can allow the subject/user to remotely operate the device of the invention. In particularly preferred embodiments, the app may provide for one or more of e.g., turning the device on and off, setting a specific predetermined temperature or predetermined temperature range for automatic operation of the device, and monitoring one or more parameters as may
30 be selected from ambient air temperature, current measured temperature of, or proximal to, the genital area or in the case of a male, the surface temperature of the scrotum or estimated temperature of the testes, variation of the measured temperature with time,

length of time of current usage of the device, charge level of the device's power source, available usage time remaining, the setting of a timer for operation of the device, and/or the timer time remaining or elapsed. The app may also include a usage log allowing the user/subject to review relevant usage data such as measured temperature(s) and
5 measured temperature variation with time, as well as times and dates of usage.

Thus, in another aspect of the present disclosure there is provided a device embodied by the invention in combination with a portable electronic device programmed for control of the operation of the device and most typically, for display and/or storage of data and/or one or more measured or operational parameters of the
10 device.

In yet another aspect, there is provided a portable electronic device programmed for control of the operation of a cooling device embodied by the invention and most typically, display and/or storage of data and/or one or more measured or operational parameters of the device.

15 Typically, the portable electronic device is configured for wireless connectivity to the cooling device.

Typically, the control system of a cooling device embodied by the invention comprises a microcontroller for controlling operation of the at least one fan of the device. In particularly preferred embodiments, the microcontroller is configured for
20 operation of the fan in response to the temperature measured by the at least one temperature sensor.

In embodiments provided with a humidity sensor for measuring humidity in proximity to the genital area of the subject, the microcontroller can be configured for controlling operation of the at least one fan on the basis of output data from the
25 temperature sensor and/or the humidity sensor. In embodiments including a humidity sensor, the operation of the fan(s) may be controlled by the microcontroller on the basis of the temperature and humidity measured by the temperature sensor and humidity sensor.

In the latter instance where the fan(s) are operated by the microcontroller on the
30 basis of output data from both the temperature sensor and the humidity sensor, the microcontroller can be configured to control the operation of the fan(s) in accordance with a pre-programmed temperature-humidity index (HTI). Typically, in such

embodiments, the microcontroller is configured for operation of the at least one fan at a speed correlated with the humidity measured by the humidity sensor.

Most typically in such embodiments, the microcontroller is configured for operation of the at least one fan at one or more progressively higher speed levels that
5 are respectively correlated with increasingly higher level(s) of humidity measured by the humidity sensor.

In particularly preferred embodiments, the cooling device is configured for operation of the device wirelessly via a software application (app) installed on an electronic device e.g., a smart phone or other portable electronic device.

10 Typically, the humidity sensor is for measuring relative humidity in proximity to the genital area of the subject.

Typically, the control system of the cooling device further comprises the a wireless connectivity module configured to interface with the microcontroller of the control system for wireless connection between the control system of the device and the
15 app.

Most typically, the wireless connectivity module is a Bluetooth™ module for Bluetooth™ connectivity between the cooling device and the app, though any other suitable wireless connectivity module may also be utilised.

In other embodiments, a device as described herein may be configured for
20 receiving a removable data storage device (e.g., a removable memory card) for recording of data from use of the device as described above for later downloading and viewing of the data from the storage device on an external digital device (e.g., a computer).

In yet another embodiment, the present invention provides for a device as described herein for cooling and/or regulating the temperature of the genital area of a
25 subject, the device being programmed or programmable for controlling operation of the device to affect the cooling and/or regulation of the temperature of the genital area.

When the predetermined temperature of the genital area is reached with use of device as described herein, the operation of the one or more fans of the device may either be stopped or operated to reduce air flow to the genital area via the ducting to
30 only a percentage of the normal air flow obtained by the fan(s). The fan(s) may also be operated at intervals for maintaining the surface temperature of genital area at a predetermined temperature or within a predetermined temperature range, which may

comprise operation of the fan at only partial speed, at normal speed, or at combinations of the foregoing as required to maintain or achieve the desired air flow and/or predetermined temperature.

5 The cooling device of an embodiment of the invention as described herein can be inserted down the front of the underwear of the subject and be retained in position by the underwear whilst the device is worn by the subject. In particularly preferred embodiments, the device can be inserted into a pouch provided in underpants or other undergarment for retention of the device in position within the pouch. Alternatively, strap(s) and/or belt(s) may be used with the cooling device to assist retention of the
10 device in position.

The one or more sensors for measuring the temperature of, or in proximity to, the genital area will normally be located in line of sight with the genital area. In instances wherein the device is located in a pouch of an undergarment worn by the subject, the pouch may comprise a mesh or other appropriate divider layer separating
15 the sensor(s) from direct contact with genital area whilst permitting the temperature measurement by the temperature sensor(s).

A device in accordance with the present invention has application to regulating the temperature of the testes of a male subject for one or more outcomes as may, for example, be selected from the group consisting of treatment or prophylaxis of heat
20 induced infertility, subfertility, testicular hyperthermia and/or aberrant sperm morphology arising from testicular hyperthermia or elevated testicular temperature, the treatment or prophylaxis of sperm DNA fragmentation, increasing sperm count, improving or increasing progressive or other sperm motility, increasing sperm viability, and improving semen and/or seminal fluid quality. Hence, a device and method as
25 described herein may find use in treating or ameliorating various aspects of male infertility or sub-fertility, and/or aspects pertaining to achieving a successful pregnancy.

Advantageously, in one or more embodiments of a device in accordance with the invention, the device may provide for ease of use, and control and regulation of the temperature of the genital area within a desired predetermined temperature range. As
30 the device can be worn by the subject while the device is in operation, in at least some embodiments, the subject may play sport, carry on with their work or otherwise go about their normal daily routine whilst wearing the device. Advantageously also, a

device as described herein can be provided in a slim or relatively unobtrusive design or configuration. Further, by operating the fan(s) of the device in a stop/start fashion and/or by controlling the speed of the fan(s) as described herein, the charge of the power source may be conserved allowing for extended operation the device.

- 5 Additionally, the use of a device in accordance with the present disclosure can avoid the use of a Peltier cooler and chiller/ice pack(s), and the limitations and disadvantages associated with the use of such cooling systems.

 The term “regulating” and alternate forms thereof such as “regulate” and “regulation” as used herein in the context of the temperature of the genital area or testes
10 of the subject as applicable, is/are to be taken in its broadest sense to include controlling the temperature of the genital area, reducing the temperature of the genital area and/or inhibiting the temperature of the genital area from increasing, whether or not in response to measured temperature(s), or set or programmed operating parameters or features of the cooling device.

- 15 Throughout this specification the word “comprise”, or variations such as “comprises” or “comprising”, will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers, integers or steps.

 Any discussion of documents, acts, materials, devices, articles or the like that has
20 been included in this specification is solely for the purpose of providing a context for the invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the invention as it existed in Australia or elsewhere before the priority date of this application.

- 25 The features and advantages of the present invention will become further apparent from the following detailed description of exemplary embodiments of the invention together with the accompanying drawings. In at least some embodiments, components or features that are common to them may be identified by the same numbering for ease of description.

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BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

- Figure 1** is a front view of a wearable cooling device embodied by the invention;
- 5 **Figure 2** is an isometric rear view of the cooling device of Fig. 1;
- Figure 3** is a top view of the cooling device of Fig. 2;
- Figure 4** is a bottom view of the cooling device of Fig. 3;
- Figure 5** is a front view of another embodiment of a cooling device embodied by the invention;
- 10 **Figure 6** is a rear view of the cooling device of Fig. 5;
- Figure 7** is side view of the cooling device of Fig. 6;
- Figure 8** is a top view of the cooling device of Fig. 7;
- Figure 9** is a view of the cooling device of Fig. 5 arranged in underpants;
- Figure 10** is a side view of the cooling device of Fig. 9; and
- 15 **Figure 11** is a view of the cooling device of Fig. 10 from above.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

- A wearable cooling device 10 embodied by the invention for controlling the
- 20 temperature of the testes of a male is illustrated in Figs. 1-4. The device comprises ducting consisting of ducts 12 and 14 for directing the flow of ambient air to an air delivery portion 16 for flow of the air to the genital area of the subject, in this instance the subject's scrotum. The air is drawn into the upper end 13 of each duct 12 and 14 from above trouser height under the operation of fans 18 as further described below,
- 25 and the upper end 13 of each duct is shaped to hook over the waist of the trousers worn by the subject for retention of the device in position. A perforated vent cover 15 is provided on the upper end each of the ducts 12 and 14 to prevent detritus from entry into the ducts with the operation of the fans. As also illustrated, the ducts 12 and 14 are arranged at an angle so as to converge toward one another and open in into the air
- 30 delivery portion 16 through exit vents 20 of the ducting.

As will be understood, the term “ambient air” is used herein in the general context of air from the atmosphere or air present beneath outer garment(s) or other clothing worn by the user of the cooling device.

5 The fans 18 in the embodiment shown are brushless axial fans and are housed in motor casings 22 which respectfully form part of the corresponding duct 12 or 14. As will be understood, other fan types though may be utilised in embodiments in accordance with the invention.

10 The air delivery portion 16 of the device is cupped to fit about the scrotum of the subject as best shown in Figs. 2-3 and when in position, curves under the scrotum of the subject so the scrotum sits within the curvature of the delivery portion. A removeable perforated screen 24 encloses the interior of the air delivery portion and allows the air to flow into contact with the scrotum to effect evaporative cooling of, and/or heat transfer from, the surface of the scrotum for cooling of the testes in use of the device. As will be understood, heat transfer from the scrotum can occur by
15 convection as a result of the air from the fan removing warmer air in contact with the skin and the faster the air flow the greater the rate of convective heat transfer. Advantageously, convective heat transfer for effecting cooling may be enhanced or promoted by the cupped profile of the air delivery portion in embodiments in accordance with the invention.

20 A control module 26 is electrically connected to the fans 18 and primary temperature sensors 28 via electrical cabling 29 of a length for allowing the control module to be located in an internal pocket or pouch of the underwear or trousers worn by the subject. Alternatively, the electrical cabling may be long enough to allow the control module to be retained in an external pocket of the trousers worn by the subject.
25 The control module of the embodiment shown includes a power input port 34 for connection of an external power source having a 5.1V DC 1A output such as a power bank or other rechargeable power source to the control module for electrical operation of the device as described herein. Examples of suitable such low voltage power sources that may be utilised include external lithium ion or NiCd power banks or batteries with
30 a 2200 mAH storage capacity or higher for longer operation of the cooling device 10. In other embodiments, the control module 26 can include an on-board rechargeable battery as a power source with associated charging control circuitry for the battery.

In the embodiment shown, the temperature sensors 28 are infrared sensors mounted to the cupped air delivery portion behind the screen 24 so as to face toward the subject's scrotum for measurement of the temperature of the skin surface of the scrotum. The temperature of the scrotum increases in a direction from the bottom to the neck of the scrotum and in embodiments of the invention, the temperature sensors are typically arranged to measure the temperature of a mid-region of the scrotum and most preferably, of a notional midline half-way between the bottom and neck of the scrotum.

Additionally, in the embodiment shown, a further temperature sensor in the form of a thermistor indicated by the numeral 30 is situated on a central strap 32 bridging the arms 12 and 14 of the ducting. In use, the device 10 is inserted by the user into position down the front of their underwear with the upper ends 13 of the ducting hooked over the waist of their trousers to retain the device in position with the air delivery portion cupped over the subject's scrotum. In this position, the thermistor 30 is located under the penis at the neck of the scrotum.

The control module 26 of the control system of the cooling device houses a microcontroller programmed for automatic proportional-integral-derivative (PID) control of the operation of the DC motor of each fan 18 on the basis of temperature data feedback from the temperature sensors 28. Each fan motor is provided with an on-board motor driver for accepting a low current control signal from the microcontroller and supply of power to the respective DC motor as is conventionally known. In particularly preferred embodiments, the operation of each motor is controlled via pulse width modulation (PWM). The fans 18 can be operated individually or as a pair. Generally, the fans 18 will operate in tandem as a pair and in at least some embodiments, one may be operated at a different speed to the other. As will be understood, the microcontroller forms part of the control system of the device, and the control system is operable to control the operation of the fans on the basis of data output from the infrared temperature sensors 28.

In preferred embodiments, microcontroller is programmed to operate the fans 18 to obtain a set predetermined temperature measured by the temperature sensor(s). Generally, in embodiments for cooling the scrotum, the predetermined temperature is selected in order to cool the testes to a desired temperature level below the core

temperature of the subject and/or to maintain the temperature of the testes at the desired temperature level below that of the subject's core temperature. The core temperature of a human is normally considered to be 37° C but can vary from about 36.1 °C to 37.2 °C between individuals within the general population, though core body temperature can
5 be higher in, for example, individuals engaged in strenuous exercise. In embodiments, the cooling of the testes is obtained by the flow of air to the scrotum from the air delivery portion 16 of the device.

In operation, the infrared temperature sensors 28 respectively measure the surface temperature of the scrotum. The microcontroller then determines whether input
10 data from one or both of those temperature sensors is above or below the predetermined temperature. If the data from one of the temperature sensors indicates the measured temperature is higher than the predetermined temperature, the microcontroller signals the fans to operate to flow air through the ducting to the scrotum to effect evaporate cooling and/or heat transfer from of the skin of the scrotum and thereby, cooling of the
15 testes of the subject. When the temperature measured by one or both of the infrared sensors 28 has decreased to or below the predetermined temperature, the fans are stopped or the speed of the fans is reduced to maintain cooling of the scrotum and the measured temperature at, or close to, the predetermined temperature. In the event the measured temperature of the surface (i.e., the skin) of the scrotum starts to increase
20 above the predetermined temperature, the microcontroller signals the motors to either turn on or to increase the speed of the fans to increase the flow of air to the scrotum for cooling of the scrotum to the predetermined temperature. This process is repeated as necessary for cooling the surface of the scrotum to the predetermined temperature and/or for maintaining the measured scrotum temperature at the predetermined
25 temperature, to thereby cool the temperature of the testes to the desired level/temperature and/or retain the temperature of the testes at the desired level/temperature.

Temperature data from the thermistor 30 is fed to the microcontroller via an analogue to digital converter in the control module 26. In embodiments, the
30 temperature measured by the thermistor may be used as a reference temperature for determining the speed of the fans 18 or as fall-back system for control of the fans in the event of failure of the infrared temperature sensors 28 or temperature measurement

circuitry associated with them. In other embodiments, the thermistor 30 or other such further temperature sensor may be omitted altogether. In embodiments that do include a further such temperature sensor, a thermocouple, or a further infrared or other temperature sensing device or arrangement may be employed rather than a thermistor.

5 From the above, the operation of the fans for achieving the cooling of the scrotum may be continuous or intermittent and/or be at full speed or at a reduced speed of the fans. This applies to both the initial cooling of the scrotum for obtaining the predetermined temperature and to the operation of the fans for maintaining the predetermined temperature. The reduced speed of the speeds can, for example be 10%,
10 20%, 30%, 40%, 50%, 60% 70% 80% or 90% of the full speed of the respective fan motors, depending on the rate of cooling required or as determined by the microprocessor. Additionally, only one of the fans may be operated at any one time or one of the fans may be operated at a different speed to the other fan. By reducing the speed of the fans and/or selectively operating one of the fans relative the other, the
15 charge of the battery power source in the control module may be conserved and thereby prolonged.

 A device 10 in accordance with the invention can be manually switched on and off by the user operating an on/off switch provided on the control module 26. In the most basic sense, embodiments in accordance with the invention may be provided in
20 which the cooling device is provided without temperature sensor(s) and humidity sensor(s). In devices of this type, the fan(s) can be operated at a constant speed when the device is manually switched on by the user until the device is manually switched off. In such embodiments, the control system of the device may, for instance, simply comprise the on/off switch itself and associated electrical wiring of the switch.

25 In particularly preferred embodiments, the operation of the device can be controlled via the use of a software application (app) installed on a portable electronic device such as a smartphone via wireless connectivity with the cooling device 10 of the invention, most usually via a Bluetooth™ connection though other suitable systems as conventionally known for effecting a personal wireless connection with the device 10
30 may be utilised besides Bluetooth™ technology (Bluetooth SIG, Inc. Kirkland, WA, USA). In the presently described embodiments, the control system of the device 10

includes a Bluetooth™ module that interfaces with the microcontroller of the control module 26.

In at least some embodiments, the app may allow the user to wirelessly set the predetermined temperature or predetermined temperature range for operation of the device and for instance, permit the user to turn the device on and off, set a specific predetermined temperature or predetermined temperature range for automatic operation of the device and/or monitor one or more parameters as may be selected from ambient air temperature, current measured temperature of the genital area or in the case of a male, the surface temperature of the scrotum or estimated temperature of the testes, variation of the measured temperature with time, length of time of current usage of the device, charge level of the device's power source, available usage time remaining, the setting of a timer for operation of the device, and/or the timer time remaining or elapsed. The app may also include a usage log allowing the user/subject to review relevant usage data such as measured temperature(s) and measured temperature variation with time, as well as times and dates of usage, and all such combinations and permutations of the above-mentioned functionalities are expressly encompassed.

Whilst embodiments as specifically exemplified herein have been described in the context of being for use by a male subject, embodiments in accordance with the invention can also be provided for use with females for increased comfort of the genital area whilst playing sport or for any reason were the wearing of a device as described herein may be helpful.

A device as described herein may be provided for cooling the temperature of the genital area by 1 °C to 1.5 °C or greater e.g., 1.5, 2, 2.5, 3, 3.5, 4, 4.5 or 5°C or more.

The predetermined temperature reached by operation of fans of the device will typically be about 36, 35.5, 35, 34.5, 34, 33.5, 33, 32.5, 32, 31.5, 31, 30.5, 30, 29, 28, 27, 26 or about 25 °C or less. In embodiments, the predetermined temperature can be a discrete temperature or a temperature range such as from 36 °C, 35 °C or 34 °C to about 25 °C or less, or any temperature or temperature range therebetween.

In the case of a male where the device is worn for the treatment or prophylaxis of fertility, sub-fertility or for fertility related purpose(s) as described herein, the device will usually be operated to reduce the temperature of the testes by 1 or more degrees to below the core temperature of the subject, and preferably to a temperature within a

range of from about 2 to 6 °C below the subject's core body temperature, preferably to within a temperature range of from 36 to about 32, 31.5, 31, 30.5 or 30 °C or less and most preferably, to within a range of from about 34.5 to 33.5 °C, e.g., about 34 °C.

Typically, a device embodied by the invention is operated to reduce the measured
5 temperature of the skin/surface of the scrotum of a subject for a fertility related purpose as described herein to a predetermined temperature in a range of from about 36 to 33, 31 or 30 °C, 35.5 to about 30 °C, more usually in a range of from about 35.5 to about 32 °C and most usually, in a range of from about 35 to about 33 °C, e.g., about 34 °C.

The above-described embodiments of the exemplified device 10 are provided
10 with converging ducts 12 and 14. In other embodiments, however, a device in accordance with the invention can have a different ducting configuration for flowing air to the air delivery portion of the device. For example, the ducting may comprise a generally "T" shaped configuration with a top, generally horizontally oriented duct that opens at its opposite ends for intake of ambient air and which is intersected in its
15 middle region by a downwardly directed duct section of flowing the air to an air delivery portion as described above. In this instance, the top duct may be slightly bowed in the horizontal plane to conform to the contour of the waist region of a user and a fan can e.g., be disposed in the downwardly directed duct for drawing the air into the ducting. In still another embodiment, the ducting may simply comprise only a
20 downwardly directed duct (an "I" ducting configuration) for flowing air drawn into the duct down to the air delivery portion in use, again under the action of a fan disposed in the downtube. Various ducting configurations are therefore possible, and all are expressly provided for herein. In such devices, the ducting can also be configured to hook over the top of trousers, or the device may otherwise be provided with hook(s) or
25 other means for hooking or fitting over the top of trousers or other clothing garment worn by the user to assist retention of the device in position. However, any other suitable systems for retaining the device in position may be utilised, including e.g., the use of belt(s) and/or strap(s).

As will also be understood, embodiments may be provided in which the ambient
30 air flowed to the genital area by the fans may be derived from below the genital area rather than from above trouser height.

In still further embodiments in accordance with the present disclosure
embodiments of the invention are also provided for flowing air that is sourced from
groin height to the genital area externally of an undergarment (e.g., underpants) under
which the cooling device is worn by the user. An example of this type of embodiment
5 is illustrated in Figs. 5 to 11.

As shown in Fig. 5, the cooling device 36 of this embodiment also comprises a
pair of fans 18 for passing air through ducting 12 and 14 into the interior of the cupped
air delivery portion 16 from the exit vents 20 of the ducting for flow over the genital
area to be cooled, which in this instance is again the scrotum of a male user. In this
10 embodiment though, the air is drawn from under the trousers or other outer garment of
the user rather than from above trouser/waist height, as illustrated in Figs. 8-11 as
further described below. The ducting 12 and 14 of this embodiment is therefore
substantially truncated compared to the embodiment illustrated in Figs. 1-4. Each fan
18 is also mounted externally to the inlet end of the respective duct 12 or 14 rather than
15 disposed within the ducting as in the embodiments described above. More particularly,
in the present embodiment, each fan 18 is mounted in a respective fan enclosure 38
secured by fasteners to a corresponding backing mount 40 integrally formed with the
ducting 12 or 14. In the particular embodiment illustrated, an environmental sensor for
measuring temperature and relative humidity about the scrotal/genital area is used
20 rather than infra-red sensor(s) for monitoring the temperature of the surface of the
scrotal/genital area as in the embodiments described above, the operation of the fans
again being controlled by data output from the environmental sensor as described
herein for cooling of the surface of the scrotum/genital area. In the illustrated
embodiment, the sensor (not shown) is located in the cavity 42 formed in the interior
25 face of the cupped air delivery portion 16 of the device.

The environmental sensor in such embodiments can for instance comprise a
capacitive humidity sensor for measurement of relative humidity and a thermistor e.g.,
a negative temperature coefficient (NTC) thermistor wherein change in the electrical
resistance of the thermistor is used to determine the ambient temperature about the
30 genital area/scrotum. Such environmental sensors useful in embodiments described
herein include commercially available DHT11 sensors (e.g., Mouser Electronics, Inc.,
Mansfield, TX 76063-1514, USA) comprising an 8-bit microcontroller and configured

for outputting calibrated digital values of temperature and relative humidity as serial data with calibrated coefficients stored in one-time programmable (OTP) memory.

DHT11 sensors for instance are capable of measuring relative humidity in a range of from 20% to 90% and temperature in a range of from 0°C to 50°C. Other suitable

5 environmental sensors comprising humidity and temperature sensor components may also be utilised in embodiments described herein. In still further embodiments, separate sensors for the measurement of temperature and relative humidity can be employed rather than a single component comprising both types of sensors as described above.

The cooling device 36 is connected to the control module 26 and a power bank
10 (e.g., a rechargeable battery pack) 44 via electrical cabling 29 though in other embodiments, the power source can be incorporated into the control module as in embodiments of the type shown in Fig. 1. As with embodiments illustrated in Figs. 1-4, the device of Fig. 5 is controlled via the use of an app installed on a portable electronic device, typically a smartphone via wireless connectivity, such as but not
15 limited to Bluetooth™ providing for functionalities via the app as with an embodiment of the type of Figs. 1-4, including display of the current temperature and/or relative humidity of the genital area measured by the environmental sensor of the device.

The measurement of relative humidity provides both a measure of comfort and a means for assessing the risk of heat stress on spermatogenesis and/or sperm motility or
20 viability in the male and in embodiments described herein, the relative humidity measured by the environmental sensor can be used to control operation of one or both of the fans 18 independently of the measured temperature or in combination with the measured temperature via the control system of the device. Likewise, one or both of the fans 18 can be operated on the basis of the temperature measured by the
25 environmental sensor independently of the relative humidity data output by the sensor, and in embodiments described herein the user may select the fan operation mode from a number of different modes providing for different ones of the above possibilities.

In particularly preferred embodiments, the operation of the fans 18 is controlled via the microcontroller of the control module 26 with reference to a temperature-
30 humidity index (THI) for optimised cooling of the environment about the genital area or scrotum. For instance, if a given temperature of 34°C is measured by the temperature sensor component of the environmental sensor and a relative humidity of

below 30% is measured by the relative humidity sensor, the fans may be operated at 10-30% of the maximal power for cooling of the genital area/scrotum to the predetermined temperature. Similarly, if the relative humidity is measured at 40-60% at this temperature the fans 18 may be operated at 40-80% of maximal power and if the
5 relative humidity is measured at 70% or above, the fans 18 may be operated at maximal power/speed. As the measured temperature cools, the speed of the fans may likewise be progressively slowed in stepwise fashion or stopped by the control system microcontroller of the control module 26, depending on the temperature measured by the environmental sensor (or other temperature sensor in the instance separate
10 temperature and humidity sensor components are utilised). As will also be understood, as the measured temperature decreases, the fans may also be operated at proportionately slower speed(s) correlated with the measured relative humidity for a lower given temperature, and all such arrangements are expressly provided for herein.

Additionally, a cooling device in accordance with the present disclosure may
15 only comprise a single electrically powered cooling fan 18 rather than a pair of fans 18 as shown in the currently illustrated embodiment.

The ducting of a device embodied by the invention is typically fabricated from a plastics or silicone material with sufficient resilience for allowing flexing and bending of the ducting in use while maintaining the passageway(s) of the ducting open, and may
20 be reinforced with spring(s), ribbing and/or corrugations for this purpose. The air delivery portion 16 may though be fabricated from a softer and more pliable plastics material for comfort of the subject when the device is, for example, being worn by a male for fertility related purposes such as the treatment or prophylaxis of infertility or subfertility, or for increasing sperm count, or improving sperm motility or semen
25 quality, or for reducing sperm DNA fragmentation as may increase as a result of prolonged exposure to elevated scrotal temperature. In other embodiments in which the device is to be worn during sporting activities such as cricket, baseball or hockey, the air delivery portion 16 of a device as described herein may in at least some embodiments, be configured to cover the full genital area of the subject (i.e., the penis
30 and scrotum in the case of a male) and be fabricated from a stiff plastics material to protect the subject against impact injury to the genital area. In such embodiments, the ducting may be formed from a resilient plastics material to allow for flexing of the

ducting during movement of the user. In yet other embodiments, a device in accordance with the invention may incorporate a conventional type of genital protector as part of the device.

5 In further embodiments, a device as described herein may be provided or worn within underpants or other type of undergarment for assisting in retaining the device in position over the genital area of the subject. In some embodiments, the underwear or undergarment may include an internal pouch for receiving the device when inserted down the front of the undergarment when worn. In such embodiments, the pouch may comprise a fabric or other wearable mesh divider for separating the air delivery portion
10 of the device from the genital area whilst allowing line of sight temperature measurement of the genital area by the primary temperature measure sensor(s) 28 where an infra-red type temperature sensor is utilised. In still other embodiments, the undergarment for being worn by the subject may be connected to the device itself by any suitable fashion or means.

15 In particularly preferred embodiments, a cooling device 36 of the type shown in Fig. 5 may be provided in combination with underpants or other type of undergarment as illustrated in Figs. 9-11. As shown, the air delivery portion 16 of the device is located within the undergarment in this instance underpants 46, with the fans exposed externally of the undergarment at groin height for flowing air present under the user's trousers (or e.g., shorts) through the ducting 12 and 14 of the device into contact with
20 the user's genital area/scrotum as applicable. In the embodiments shown, the fan enclosures are fitted through corresponding stretchable openings provided in the undergarment though any other suitable arrangement for drawing in the ambient air present externally of the undergarment at groin height from beneath trousers or other
25 outerwear worn by the user can be employed. As will be understood, the openings through which the fan enclosures 38 protrude can be elasticised for assisting insertion of the fan enclosures into the openings and retention of the device in position. Strap(s) and/or belt(s) may also be fitted to the cooling device for being worn about the waist and/or upper thigh(s) of the user to assist retention of the device in position.

30 The electrical cabling 29 connecting the cupped air delivery portion 16 to the control module 26 (and power source when provided separately from the control

module 26) can be of a length for allowing the control module (and power source) to be located in a pocket or pockets of e.g., trousers or trouser shorts worn by the user.

In further embodiments, a cooling device as described herein may be configured for receiving a removable data storage device (e.g., a removable memory card such as a
5 Secure Digital (SD) card or Multi-Media card (MMC)) for recordal of data from use of the device as described above for later removal of the data storage device and downloading and viewing of the data from the storage device on an external digital device (e.g., a computer). In particularly preferred embodiments, the control module 26 can be provided with a port for insertion of the removeable data storage device for the
10 purpose of recordal of the data on the storage device.

In still further embodiments, a cooling device in accordance with the present disclosure may be provided in which the fan(s) of the device are turned on or off as desired by manual operation of the on/off switch provided on the control module 26. That is, embodiments can be provided without any temperature sensors at all for
15 measuring the temperature of the genital area and once switched on, the fan(s) run until switched off by the user either by operation of the on/off switch or via an app as discussed above. Further, in embodiments, the fan(s) may be operated at any speed up to full speed as required or as selected by the user.

In yet other embodiments, the cooling device can be operable at one or more
20 modes selected by the user, for example a continuous mode without a present temperature wherein speed of the fan(s) is preset or can be set by the user, and a further mode wherein the user can set the predetermined temperature and the device operates automatically in response to temperature measured by the temperature sensor (and humidity sensor when provided) as described herein.

25 Additionally, as described above, embodiments of a cooling device in accordance with the instant disclosure may be configured for the at least one temperature sensor to measure temperature in proximity to the genital area, such as proximal ambient temperature rather than surface temperature of the genital area, or a combination of temperature in proximity to the genital area and the surface temperature
30 of the genital area, and the fan(s) of the device operated on the basis of the measured temperature(s). In embodiments in which the ambient temperature proximal to the genital area is measured, the measured temperature may provide an indicative

temperature of the genital area, and the fan(s) of the device can be operated accordingly. In embodiments, the proximal ambient temperature measured can be that between the air delivery portion 16 and the genital area. The at least one temperature sensor or such embodiments may be a thermistor or other suitable temperature sensor
5 such as an environmental sensor including a suitable temperature sensor for this purpose.

It will also be understood that the control module 26 may implement any suitable processing unit for processing the relevant sensor data/messages and may include a microprocessor, microcontroller, programmable logic device or other
10 computational device, a general-purpose computer or a server computer.

Further, the various aspects described herein may be implemented via any appropriate number and/or type of computer platform, modules, processors, memory, etc. each of which may be embodied in hardware, software, firmware, middleware and the like.

15 Whilst the invention has been described above in the context of controlling the temperature of the testes of a human male, the invention is not limited thereto and embodiments extend to the provision and use of appropriately configured devices as methods as described herein with any scrotum bearing male animal such as an equine animal (e.g., a thoroughbred race horse), camel or member of the bovine, ovine,
20 porcine, feline, canine or primate animal families.

From the above description it will be apparent a device or method in accordance with the invention may provide one or more advantages as may be selected from:

- Ease of use and operation of the device;
- 25 • Automatic temperature control of the genital area cooled by the device;
- Intermittent fan operation providing for prolonging of battery charge and therefore operation time;
- Setting of the predetermined temperature and relative humidity for controlled operation of the fan(s);
- 30 • Remote control of the cooling device via an app on a portable electronic device and display of operational variables, parameters and usage data on the electronic device;

- Discrete use of the device whilst working or undertaking sport or other activities;
- The device in at least some embodiments being configured to assist retention of the device in position by hooking over the waist of trousers worn by the subject;
- Avoidance of the use of chilled/ice packs for cooling purposes; and
- Not the least, treatment or prophylaxis or infertility, subfertility, increasing sperm count, reducing aberrant sperm morphology, increasing progressive or other sperm motility, decreasing sperm DNA fragmentation, increasing sperm viability, and/or improving semen and/or seminal fluid quality.

Although a number of embodiments of the invention have been described above it will be understood that various modifications and changes may be made thereto without departing from the invention. The embodiments described above are therefore only illustrative and are not to be taken as being limiting or restrictive.

CLAIMS

1. A wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:
 - 5 an air delivery portion configured for being fitted about the genital area; and
at least one electrically powered fan arranged for flowing air to the air delivery portion for contact with the genital area to cool the genital area with operation of the fan.
 2. The cooling device of claim 1, wherein the at least one fan is arranged for
10 flowing the air to the genital area of the subject from externally of an undergarment in which the cooling device is worn by the subject in use of the device.
 3. The cooling device of claim 1 or 2, further comprising ducting for directing the flow of air from the at least one fan to the air delivery portion, the ducting opening into the air delivery portion for said flow of the air into contact with the genital area.
 - 15 4. The cooling device of claim 3, wherein the at least one fan is arranged in the ducting of the device for flowing the air through the ducting into the air delivery portion.
 5. The cooling device of claim 3, wherein the at least one fan is mounted externally of the ducting for flowing the air through the ducting into the air delivery
20 portion for contact with the genital area.
 6. The cooling device of claim 3, wherein the device is configured to draw the air from above trouser height of the subject for said flow of the air to the air delivery portion for contact with the genital area with the operation of the at least one fan.
 7. The cooling device of claim 4, wherein the device is configured to draw the air
25 from groin height of the subject external to an undergarment worn by the subject, for said flow of the air to the delivery portion for contact with the genital area with the operation of the at least one fan.
 8. The cooling device of any one of claims 2 to 7, comprising a pair of ducts and a pair of fans, one of the fans being arranged to flow the air through a corresponding one
30 of the ducts, respectively.
 9. The cooling device of any one of claims 1 to 8, wherein the air is ambient air.

10. The cooling device of any one of claims 1 to 9, wherein the air delivery portion is shaped to cup the subject's genital area when the device is worn by the subject.
11. The cooling device of any one claims 1 to 10, further comprising a control system operable to control the operation of the fan.
- 5 12. The cooling device of claim 11, further comprising at least one temperature sensor for measuring temperature of, or in proximity to, the genital area, and wherein the control system is operable to control the operation of the at least one fan in response to the temperature measured by the at least one temperature sensor.
- 10 13. The cooling device of claim 12, wherein the at least one temperature sensor is for measuring surface temperature of the genital area.
14. The cooling device of claim 12, wherein the at least one temperature sensor is for measuring temperature in proximity to the genital area.
15. The cooling device of claim 13 or 14, further comprising a humidity sensor for measurement of humidity in proximity to the genital area, and wherein the at least one fan is operable to start or increase the flow of air to the genital area in response to the temperature measured by the temperature sensor, and wherein the speed of the fan is controlled by the control system to correlate with the humidity measured by the humidity sensor.
- 15 16. The cooling device of claim 15, wherein the humidity sensor is for measurement of relative humidity.
- 20 17. The cooling device of any one of claims 12 to 14, wherein the at least one fan is operable to start or increase the flow of air to the genital area when the temperature measured by the at least one temperature sensor is above a predetermined temperature and to reduce or stop the flow of air to the genital area as the measured temperature decreases, or the measured temperature approaches, reaches or falls below the predetermined temperature.
- 25 18. The cooling device of claim 15 or 16, wherein the at least one fan is operable to start or increase the flow of air to the genital area when the temperature measured by the at least one temperature sensor is above a predetermined temperature.
- 30 19. The cooling device according to claim 17 or 18, wherein the control system is operable to reduce or stop the flow of air to the genital area as the measured

temperature decreases, or the measured temperature approaches, reaches or falls below the predetermined temperature.

20. The cooling device of any one of claims 16 to 19, wherein the subject is a male and the genital area is the scrotum of the subject, and wherein the predetermined
5 temperature is a temperature for cooling the temperature of the testes to below and/or maintaining the temperature of the testes below, the core body temperature of the subject.

21. The cooling device of claim 20, wherein the predetermined temperature is a temperature for cooling the temperature of the testes to and/or maintaining the
10 temperature of the testes at, about 1°C or more below the core body temperature of the subject.

22. The cooling device of any one of claims 17 to 21, wherein the predetermined temperature is a temperature within a predetermined temperature range.

23. The cooling device of claim 22, wherein the predetermined temperature range is
15 from about 29 °C to about 35 °C, inclusive.

24. The cooling device of any one of claims 11 to 23, wherein the control system of the cooling device comprises a microcontroller for controlling the operation of the at least one fan in response to the temperature measured by the at least one temperature sensor.

20 25. The cooling device of claim 15 or 16, wherein the control system of the cooling device comprises a microcontroller for controlling the operation of the at least one fan based on the temperature measured by the temperature sensor and/or the humidity measured by the humidity sensor.

26. The cooling device of any one of claims 1 to 19, wherein the subject is male and
25 the genital area is the scrotum of the subject.

27. A wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising;

an air delivery portion for being fitted about the genital area for delivery of air flow into contact with the genital area for cooling of the genital area by the air flowing
30 into contact with the genital area;

at least one electrically powered fan arranged for flowing the air to the air delivery portion with operation of the fan; and

a control system operable to control the operation of the fan.

28. A wearable cooling device for regulating the temperature of an external genital area of a subject, the device comprising:

- 5 ducting for directing air flow to the genital area;
 at least one electrically powered fan arranged for flowing the air along the
ducting into contact with the genital area with operation of the fan; and
 a control system operable to control the operation of the fan.

29. A wearable cooling device for regulating the temperature of an external genital
10 area of a subject, the device comprising:

- at least one electrically powered fan arranged for flowing air into contact with
the genital area with operation of the fan;
 at least one temperature sensor for measuring temperature of, or proximal to, the
genital area; and
15 a control system operable to control the operation of the fan in response to the
temperature measured by the temperature sensor.

30. A wearable cooling device for regulating the temperature of the testes of a male
subject, comprising:

- ducting for directing air flow to the scrotum of the subject;
20 at least one electrically powered fan arranged for flowing the air along the
ducting into contact with the subject's scrotum with operation of the fan;
 at least one temperature sensor for measuring temperature of, or proximal to, the
scrotum; and
 a control system operable to control the operation of the fan in response to the
25 temperature of the surface of the scrotum measured by the at least one temperature
sensor, while the device is being worn by the subject.

31. A method for cooling the temperature of an external genital area of a subject,
comprising:

- providing a wearable cooling device for being worn by the subject to cool the
30 genital area of the subject, the cooling device comprising an air delivery portion for
being fitted about the genital area for delivery of air flow into contact with the genital
area, at least one electrically powered fan arranged for flowing the air to the air delivery

portion with operation of the fan, and a control system operable to control the operation of the fan;

fitting the device to the subject; and

operating the control system of the device for operation of the fan to flow the air to the air delivery portion while the device is worn by the subject.

32. A method for cooling an external genital area of a subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the genital area of the subject, the cooling device comprising ducting for directing air flow to the genital area, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the genital area with operation of the fan, and a control system operable to control the operation of the fan;

fitting the device to the subject; and

operating the control system of the device for operation of the fan to flow the air to the genital area while the device is worn by the subject.

33. A method for regulating the temperature of an external genital area of a subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the genital area of the subject, the cooling device comprising at least one electrically powered fan arranged for flowing air into contact with the genital area with operation of the fan, at least one temperature sensor for measuring temperature of, or proximal to, the genital area, and a control system operable to control the operation of the fan in response to the temperature measured by the temperature sensor;

fitting the device to the subject; and

operating the control system of the device to control the operation of the fan in response to the temperature measured by the at least one temperature sensor, while the device is worn by the subject.

34. A method for regulating the temperature of an external genital area of a subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the genital area of the subject, the cooling device comprising ducting for directing air flow to the genital area, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the genital area with operation of the fan, at least

one temperature sensor for measuring temperature of, or proximal to, the genital area, and a control system operable to control the operation of the fan;

fitting the device to the subject; and

operating the control system of the device to control the operation of the fan in response to the temperature measured by the at least one temperature sensor, while the device is worn by the subject.

35. The method of any one of claims 31 to 34 wherein the subject is a male and the genital area is the scrotum of the subject.

36. The method of claim 35, wherein the method is for regulating the temperature of the testes of the subject.

37. A method for regulating the temperature of the testes of a male subject, comprising:

providing a wearable cooling device for being worn by the subject to cool the surface temperature of the scrotum of the subject, the cooling device comprising ducting for directing air flow to the scrotum, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the subject's scrotum with operation of the fan, at least one temperature sensor for measuring the surface temperature of the scrotum, and a control system operable to control the operation of the fan;

fitting the device to the subject; and
operating the control system of the device to control the operation of the fan in response to the temperature of the surface of the scrotum measured by the at least one temperature sensor, while the device is worn by the subject.

38. A method for regulating the temperature of the testes of a male subject, comprising:

fitting a wearable device to the subject for cooling the scrotum of the subject, the cooling device comprising ducting for directing air flow to the scrotum, at least one electrically powered fan arranged for flowing the air along the ducting into contact with the subject's scrotum, at least one temperature sensor for measuring temperature of, or about, the scrotum, and a control system operable to control the operation of the fan;
and

operating the control system of the device to control the operation of the fan in response to the temperature measured by the at least one temperature sensor, while the device is worn by the subject.

39. The method of any one of claims 36 to 38, wherein the method is for regulating
- 5 the temperature of the testes for one or more outcomes selected from the group consisting of treatment or prophylaxis of heat induced infertility, subfertility, testicular hyperthermia and/or aberrant sperm morphology arising from testicular hyperthermia, treatment or prophylaxis of sperm DNA fragmentation or DNA damage, increasing sperm count, improving or increasing progressive sperm motility, increasing sperm
- 10 viability, and improving seminal fluid quality.