**Title:** DEVICE AND METHOD FOR MONITORING PHYSIOLOGICAL PARAMETERS

**Abstract:** A device for monitoring physiological parameters of a user, comprising a holder (2) provided with at least one display (2a), one wearable or implantable element (400) comprising a sensor for detecting the heart rate (4) of the user during a predetermined period of time of wakefulness and/or sleep of the user, connection means (3) of the holder (2) to the wearable or implantable element (400), at least one processing unit (5) of the data detected by said sensor (4) to determine the heart rate variability HRV of the user during said predetermined period of time, said display (2a) being suitable for displaying at least one first indicator (7) of the state of psycho-physical stress of the user, in relation to said predetermined period of time, understood as a set of symptoms caused by an imbalance of the Autonomic Nervous System (ANS), said state of psycho-physical stress being determined based on the level of heart rate variability HRV detected by said sensor (4). The processing unit (5) is suitable for defining the aerobic threshold of the user and the detected state of psycho-physical stress and for generating at least one workout program for the user and/or one parameter representative of the intensity of the workout that the user must carry out in relation to the determined aerobic threshold value and level psycho-physical stress.
"DEVICE AND METHOD FOR MONITORING PHYSIOLOGICAL PARAMETERS"

TECHNICAL FIELD OF THE INVENTION

The present invention concerns a device and a method for monitoring physiological parameters. More particularly, the invention concerns a device and a method for monitoring the level of psycho-physical stress of an individual based on the determination of the parameter of heart rate variability, and for defining programs and intensities of workout suitable for such a level of stress.

PRIOR ART

Various devices are known that allow monitoring, constantly or within a given time interval set by the user, some physiological parameters of the user. The simplest and most common of these are heart rate monitors, preferably portable, which allow detecting the instantaneous heart rate of the user, for example while performing physical activity, to monitor it and extract useful information on the physical state of the user himself.

There are also other similar devices such as portable electrocardiographs, or other wearable devices in general, normally defined in the industry as "sport & fitness trackers and wearable devices".
The most modern and advanced heart rate monitors, as well as other wearable devices, in addition to detecting the instantaneous heart rate, also allow processing the data collected in a given period of time, for example by organising them into a historical archive where the user can check the evolution over time of his physical state, his performance, etc. Some heart rate monitors are, in addition, configured so as to be able to transfer the collected data, with the permission of the user, by creating his own account, on dedicated websites or portals - made, for example, by the manufacturer of the device itself - which allow the user to access a range of monitoring services and historical processing of the collected data.

Such services and processing provide a multitude of information useful for people who want to have a constant feedback on their state of health, especially those who make regular physical activity.

Following essentially the same philosophy, other similar devices for detecting the heart rate have also spread on the market, which can be connected, for example, to a smartphone or tablet, by using specific applications downloadable from the Internet.
For example, such devices comprise a sensor for detecting the heart rate, of any known type, associated with a connection interface, for example, a USB port of a smartphone, tablet, or the like, or associated with a wireless type interface, such as Bluetooth Smart technology and the like.

Through an application present on the smartphone or the tablet, the user can manage the functions of the heart rate monitor, save and transfer the collected data onto dedicated websites, and more.

In the scientific world, the importance, for assessing the individual's state of health, of the parameter of the so-called heart rate variability - hereinafter also indicated by HRV, Heart Rate Variability - understood as the phenomenon of variability of the time intervals existing between a heartbeat and another, has been known for some years.

Referring to the attached figure 9, which schematically represents the electrocardiogram trace of an individual, it is noted that normally the time intervals T1,T2,T3 existing between the various heartbeats B are not identical, but vary more or less markedly with every heartbeat.

In fact, numerous studies which have been carried out show that a low value of HRV in the individual may be
in some way linked to non-optimal health conditions, such as conditions of high psycho-physical stress; some of these studies show that even a low value of HRV may be predictive of risk after an acute myocardial infarction or an early warning sign of diabetic neuropathy.

A low value of HRV has also been proposed as a marker of many chronic diseases. The HRV parameter is therefore increasingly considered in scientific studies that concern not only specifically cardiology, but also the general assessment of the well-being state of the individual in his interaction with the environment.

As a result, some of the more advanced monitoring devices common on the market also allow measuring the HRV parameter, in a given time interval of detection of the heart rate, to provide the user with information on his general state of health.

As said, this information can then be transferred to a dedicated website where it can then be reprocessed to allow the user himself to analyse and examine in depth certain aspects related to his health.

Nowadays, the need is felt to be able to use the information related to the HRV parameter in a more
thorough and complete way as part of the daily life of each individual.

OBJECTS OF THE INVENTION

The object of the present invention is to improve the state of the art. Within this object, an aim of the present invention is to develop a device and a method for monitoring physiological parameters that allow the user to use the HRV parameter related to his heart rate in order to manage in the best and most appropriate way all the activities to be performed during the day, with special but not exclusive reference to physical workout activity.

Such an object and such aims are all achieved by a device for monitoring physiological parameters according to the attached claim 1, and by a method for monitoring physiological parameters according to the attached claim 9.

The appended claims refer to advantageous embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

These and further advantages will be better understood by anyone skilled in the art from the following description and the attached drawings, given as a non-limiting example, in which:
figure 1 is a schematic front view of a monitoring device according to the present invention;
figure 2 is a constructive-functional scheme of the device;
figure 3 is a detail of the device display;
figure 4 is a detail of the device display, according to another embodiment;
figure 5 is a schematic front view of another embodiment of the device according to the invention;
figure 6 is a schematic front view of a monitoring device according to another embodiment of the present invention;
figure 7 is a schematic front view of a monitoring device according to yet another embodiment of the present invention;
figure 8 is a schematic front view of a monitoring device according to a further embodiment of the present invention;
figure 9 is a schematic representation of a portion of an electrocardiogram;
figure 10 is an axonometric and schematic view of an exercise machine comprising the device according to the invention;
figure 11 is an axonometric and schematic view of an exercise machine which can be associated with the device according to the invention;
figure 12 is an axonometric and schematic view of an exercise machine onto which the data processed by the method according to the present invention is loaded;
figure 13 is a schematic perspective view of another embodiment of the device according to the invention;
figure 14 is a front view of the device holder according to the embodiment of figure 13;
figure 15 is a front view of the device holder according to another embodiment of the invention;
figure 16 is a front view of the device holder according to yet another embodiment of the invention;
figure 17 is a block diagram which represents the main operational sequence of the method of management and control of the operation of the device according to the present invention;
figure 18 is a block diagram which represents a further optional operational sequence of the method of management and control, during the performance of a workout program on exercise equipment;
figure 19 is a block diagram which represents another operational sequence of the method according to the
invention, during the performance of an incremental effort test on exercise equipment;
figure 20 is a block diagram which represents yet another operational sequence of the method according to the invention, during the user's sleep.

EMBODIMENTS OF THE INVENTION

With reference to figure 1, a device for monitoring physiological parameters according to the present invention is generally indicated by 1.

The device 1 comprises a holder 2. The holder 2 may be of a portable type, or of a type that can be installed on another device or equipment, as explained hereinafter. In case it is of the portable type, the holder 2 has a size and weight suitable for being easily transported by the user, and/or for being comfortably worn by the user.

The holder 2 comprises a respective display 2a. The device 1 further comprises connection means 3 to at least one sensor for detecting the user's heart rate 4 during a predetermined time interval. The connection means 3 are associated with the holder 2. For example, the connection means 3 may be present inside the holder 2, or even outside the holder 2 and
they can be associated with it only when the device 1 is used.

Furthermore, the connection means 3 may also be of wireless type.

More generally, connection means 3 of any type can be used without departing from the scope of protection of the present invention.

In the remainder of the present invention, the predetermined time interval during which the user's heart rate is detected via the sensor 4 is understood as any length of time established by the user, or selectable by the user among a certain number of predeterminable intervals.

For example, such a length of time may be a few minutes, a few hours, a whole day or even several days.

It is, therefore, any time interval deemed sufficient to carry out a reliable detection of the individual's HRV parameter, without any limitation.

It should also be noted that fixed time interval is not only understood as an already completed time interval - that is, having an initial moment and a final one - but also as a current time interval, that is, started at a given moment and not yet completed.

It is also understood that the above-mentioned predetermined period of time may concern both
wakefulness and sleep.
The sensor for detecting the heart rate 4 can be of any known type without any limitation, and does not constitute a specific object of the present invention, and therefore will not be further described in detail.

For example, the sensor 4 may be of the band type, or also of another wearable or implantable type.

More in detail, the sensor 4 can be embedded in a respective implantable or wearable element 400.

The device 1 comprises at least one processing unit 5.
The processing unit 5 is housed inside the holder 2.
The processing unit 5 has mainly, but not exclusively, the function of processing the data acquired by the sensor for detecting the heart rate 4, during the above-mentioned predetermined time interval.

As better explained in the following, the processing of the data acquired by the sensor for detecting the heart rate 4 allows determining the user's heart rate variability HRV during the above-mentioned predetermined time interval.

According to an aspect of the present invention, the above-mentioned processing unit 5 is suitable for defining, based on the previously determined HRV parameter, the aerobic threshold of the user associated with the above-mentioned time interval.
Aerobic threshold is understood as the level of physical exercise intensity wherein an increase in the concentrations of lactate (2 mmol/l) higher than baseline levels and the activation of fast-twitch muscle fibres in support of the slow-twitch fibres to bear the effort occur. Furthermore, the processing unit 5 of the device 1 is suitable for generating at least one workout program for the user in relation to the above-mentioned aerobic threshold, and/or one parameter representative of the intensity of the workout that the user can carry out in relation to the above-mentioned aerobic threshold, and in relation to his conditions of psycho-physical stress.

The above-mentioned aerobic threshold, also determined based on the knowledge of the HRV parameter, varies significantly depending on the individual's level of psycho-physical stress. It is noted that the expression psycho-physical stress is understood as the syndrome of adaptation to a set of external stresses, or stressor agents, which may be physiological, but which may have pathological, even chronic, implications, which fall into the field of psychosomatics.

It is also noted that such an expression is not
intended as a condition of effort due to the performance of physical activity during the time interval of heart rate detection.

The above-mentioned stressor agents can be, for example, physical (electric shock, thermal shock, etc.) or of environmental-cultural type (noise, traffic, etc.), or even metabolic, psychological, emotional, food-related, and so on, without particular limitations.

Even more generally, psycho-physical stress is understood as a set of symptoms caused by an imbalance of the Autonomic Nervous System (ANS) that result in a state of user inconvenience in various aspects of daily life, not only during the performance of physical exercise.

This important aspect will be further explained and discussed in detail in the remainder of the description.

According to another aspect of the invention, which will be better explained hereinafter, the processing unit 5 is suitable for generating and displaying on the display 2a of the holder 2 a message related to the qualitative assessment of the behaviours of the user during sleep.

The processing unit 5 is associated with an internal
memory 6 of the device 1, which contains any pre-installed, or user-installed, software applications, and the data collected by the sensor 4. According to another aspect of the present invention, the holder 2 of the device 1 comprises a first indicator 7 for displaying at least one indicator of the level of the user's psycho-physical stress. The first indicator 7 is provided on the outer surface of the holder 2, in particular in the display 2a. The indication of the level of psycho-physical stress in the first display 7 can be done in various ways. Referring, for example, to the embodiment of the device 1 depicted in figures 1, 3, such an indication may be carried out via a hand 8 associated with a graduated scale 9 wherein there are a minimum value and a maximum value. This is an indication that aims to provide a fast and intuitive display of the level of stress, i.e. so the individual can immediately understand if he is in a situation of low stress or high stress. In the depicted embodiment, instead, in the detail of figure 4, the indication of the level of stress is done by means of a partially filled bar 10, where the filled zone 11 corresponds to the level of stress. Of course, an indication of such a parameter may take
place by any other means, including those that are known, suitable for providing an immediate and intuitive display.

According to a further aspect of the present invention, the holder 2 of the device 1 comprises a second indicator 12 for displaying at least one workout program for the user, and/or at least one parameter representative of the intensity of the workout that the user can carry out in relation to his level of psycho-physical stress.

In particular, in the embodiment depicted in figures 1,3, the second indicator 12 indicates a parameter representative of the intensity of the workout that the user can carry out in relation to at least his level of psycho-physical stress.

The display of such a parameter can be carried out, also in this case, via a hand 8 associated with a graduated scale 9, wherein there are a minimum value and a maximum value.

Alternatively, such a display may be carried out with a partially filled bar 10, or still with other means.

In the embodiment of figure 4, instead, the second indicator 12 shows instructions 13, preferably simple, short and intuitive, relating to a specific workout program that the user can carry out.
In particular, it is preferably, but not exclusively, a workout program that the user can carry out in the hours immediately following those of the predetermined period of time wherein the HRV parameter was detected.

In other embodiments of the invention, the second indicator 12 may show mixed indications, i.e. comprising both an indication of the intensity of the workout that he can carry out, and specific instructions 13 on the specific workout program to be carried out.

The workout program that the user can carry out, which, as mentioned, is shown in a concise and intuitive manner by the second indicator 12, can be developed by the same processing unit 5 of the device 1 based on information pre-set by the user, or by a qualified trainer.

For example, in one embodiment of the device, a certain number of pre-set programs may be present in the internal memory 6 of the device 1 - already installed or subsequently inserted - selectable by the processing unit 5.

In another embodiment of the device, the programs may be stored in a dedicated website or portal - created for example by a trainer - and may be transferred - for example, daily, weekly, etc. - into the internal memory.
of the device 1 via a cabled, wireless connection, etc.

In yet another embodiment, a software application that allows the user himself, or his trainer, to create the workout programs from time to time, in a completely customisable manner, may be present in the internal memory 6 of the device 1.

The present invention therefore does not set particular limits to the origin of the workout programs, the methods of their processing development, etc.; there may be workout programs from any source and created in any way.

Only by way of example, a workout program may contain instructions 13 on the use of a specific exercise machine for a given time and with given intensity, or instructions 13 on the performance of physical activity outdoors for a given time and with given intensity, and other similar instructions.

In some cases, the instructions 13 may be mostly qualitative, that is, they may indicate to carry out exercises on a certain type of exercise machines and not on another type.

The device 1 comprises at least one interface 14, through which the user can enter specific information related to his daily activities, or perform other
functions.
Preferably, but not exclusively, the user can enter specific personal information such as his calorie intake during a predetermined time interval via the above-mentioned interface 14.
This can be done directly if the user knows precisely the calorie content of the ingested food, or indirectly through the use of any specific application software installed in the internal memory 6 of the device 1.
In addition to this, the user can enter more specific personal information that may be useful in the context of the processes that are carried out by the device 1, such as any disease from which he suffers, age, gender, weight, height, or others.
Furthermore, the user can manage any other function of the device 1 through the interface 14.
For example, the interface 14 may include an additional touch screen-type display 15, or of another type suitable for displaying and/or entering information and/or giving instructions to the device.
The interface 14 may also comprise a plurality of buttons 16, separated from the additional display 15, for the management of the main functions, for example switching on, switching off, and others.
According to yet another aspect of the invention, the
holder 2 of the device 1 comprises a third indicator 17 for displaying the calorie intake of the user during a predetermined time interval.

Even the third indicator 17 may be of the type comprising a hand 8 on a graduated scale 9, as in the embodiment of figures 1,3, or of the type comprising a partially filled bar 10, as in the embodiment of figure 4.

Any other quick and intuitive display mode can be provided for in the third indicator 17.

This indication allows the user to immediately assess the calorie content ingested, for example, during the day or in another predetermined time interval, and therefore to evaluate immediately if it is necessary to carry out physical activity to balance a potentially unfavourable situation, and hence harmful to health in terms of body weight control.

The device 1 according to the invention comprises means of detection of the movement of the user 18 during the predetermined time interval.

The above-mentioned means of detection of the movement of the user 18 can consist, for example, of a sensor of the accelerometric type associated with the processing unit 5, or of a sensor of any other suitable type and constantly detect the physical activity of the user,
for example walking, running, going up and down stairs, and the like.

According to yet another aspect of the invention, the holder 2 of the device 1 comprises a fourth indicator 19 for displaying the calorie intake of the user during a predetermined time interval.

Even the fourth indicator 19 may be of the type comprising a hand 8 on a graduated scale 9, as in the embodiment of figures 1,3, or of the type comprising a partially filled bar 10, as in the embodiment of figure 4.

Any other quick and intuitive display mode can be provided for in the fourth indicator 19.

This indication allows the user to assess at a glance the amount of physical activity carried out during a predetermined time interval, and therefore to understand immediately if the energy balance in such a time interval is favourable or unfavourable.

The device 1 comprises connection means 20 to other devices such as personal computers, mobile phones, tablets, and the like.

Such connection means 20 may consist, for example, of USB sockets, transmit-receive antennas, and the like, without any limitation, suitable for transferring data from and into the internal memory 6.
The device 1 may be provided with its own battery 21 connected to the processing unit; such a battery 21 may be, for example, of the rechargeable type.

Regarding the specific functions of the processing unit 5, the determination of the HRV parameter based on the collected heart rate data can be carried out through different calculation methods or known mathematical models which do not constitute a specific object of the present invention.

Some usable methods may be those based on the analysis of the frequency domain of the detected signal (for example Fourier transform).

In particular, some of these methods define frequency bands (for example high and low frequency) and calculate the number of time intervals that exist between heartbeats and that fall into one band or the other.

The determination of the aerobic threshold can also be carried out through different methods or mathematical models which do not constitute a specific object of the present invention, for example the Karvonen formula.

The determination of the level of psycho-physical stress based on HRV can be carried out according to different, specially arranged mathematical models.

In particular, such mathematical models can be based on
a comparison between the detected HRV parameter of the
user and typical reference values for individuals of
that profile (age, gender, etc.) found in the
literature.

The invention thus conceived allows obtaining important
technical advantages.

First, the device allows the user to obtain a correct
and precise indication about the intensity and ways of
the workout he can carry out in relation to his
conditions of psycho-physical stress, possibly also
taking into account the energy balance, between
ingested calories and burnt calories, hitherto
detected.

Such an indication on the workout to be carried out is
mainly processed based on the detected HRV parameter,
and based on the aerobic threshold in combination with
it.

Along with this, the user also has an immediate
assessment of his level of stress available, which
requires him to carry out a more or less intense
workout to still get benefits and not harm health; more
generally, such an immediate assessment of the level of
stress provides very useful information on the
individual's health.

The user can have an absolutely versatile tool that can
be interfaced with any other device, running with any operating system, and integrated with other "apps".
All this information is provided in a simple, immediate and intuitive manner thanks to the presence of the easy-to-read indicators 7,12,17,19.
All the features of the device - determination of the energy balance, detection of the physical activity, detection of the level of stress and subsequent programming of workouts - can also be used independently of each other, if the user so wishes.
In figure 5, a further embodiment of the device 1 according to the invention is depicted.
It is, in particular, a simplified embodiment in which only the first indicator 7, the second indicator 12 and an interface 14 comprising the minimum controls, that is, for example, the single button 16 for switching on and off the device, are present in the holder 1.
In this embodiment, the device 1 is designed to provide the user with only the information related to the level of psycho-physical stress 13 and the instructions of the workout program to be carried out suitable for his conditions of stress.
In this embodiment, the ability of the device to provide immediate and intuitive indications, to allow the user to behave properly in relation to his
conditions without having to carry out further investigations or analyses, is further increased.

Yet a further embodiment of the device according to the invention is depicted in figure 6.

It is, in particular, another simplified embodiment wherein, instead of the third indicator 17 and the fourth indicator 19, a single fifth indicator 19a may be provided, which summarises the energy balance of the user during a predetermined time interval.

For example, such a single indicator 19a may be of the partially filled bar type where the half-filling represents the energy balance between the ingested calories and burnt ones, while moving the filled portion to the left or right may indicate, respectively, an imbalance in the sense of the ingested calories or burnt ones.

Alternatively, the indicator 19a may be of the type with a hand on a graduated scale, where the central position of the hand is the energy balance.

No other indicators are provided on the device 1.

The workout programs formulated by the processing unit 5, or the possible indications about the intensity of the workout, can be stored in the internal memory 6 and be displayed in other ways, for example through connection to another device such as a PC, a tablet or
Yet a further embodiment of the device according to the invention is depicted in figure 7. It is a further simplified embodiment wherein two indicators are provided, that is, the first indicator 7 for displaying the state of psycho-physical stress of the user, and the fifth indicator 19a, described in the previous embodiment, which summarises the energy balance of the user during a predetermined time interval.

The device 1, according to the present embodiment, thus provides a useful alternative for users who want to have a simple object, yet still able to provide essential information for some user profiles.

No other indicators are provided on the device 1.

In this case, too, the specific workout programs formulated by the processing unit 5, or the possible indications about the intensity of the workout, can be stored in the internal memory 6 and be displayed in other ways, for example through connection to another device such as a PC, a tablet or the like.

In figure 8, another embodiment of the device 1 according to the invention is depicted.

It is yet another simplified embodiment wherein three indicators are provided, that is the first indicator 7 for displaying the state of psycho-physical stress of
the user, the third indicator 17 for displaying the calorie intake of the user in a predetermined time interval, and a fourth indicator 19 for displaying the movement of the user in a predetermined time interval.

It is therefore an alternative to the previous embodiment, where the calorie intake and physical activity are displayed independently of each other instead of the caloric balance.

No other indicators are provided on the device 1.

In this case, too, the specific workout programs formulated by the processing unit 5, or the possible indications about the intensity of the workout, can be stored in the internal memory 6 and be displayed in other ways, for example through connection to another device such as a PC, a tablet or the like.

In an alternative embodiment of the invention, schematically depicted in figure 10, the device 1 can be embedded in an exercise machine 22, for example a treadmill or the like, instead of being portable, or wearable.

In particular, the device 1 can be associated with the processing unit of the exercise machine 22, and its operation can be managed using the same user interface 23 of the machine 22 or via another dedicated user interface.
In this case, the device 1 is operated whenever the user gets on the exercise machine 22, or stands in its vicinity anyhow. This embodiment may be particularly advantageous in case the user wishes to know his own conditions and his level of psycho-physical stress immediately before starting the workout, so as to be able to train in the most appropriate way without harming his own health. Otherwise, this embodiment may be particularly advantageous in case the user already knows, on a given day, his level of psycho-physical stress, since he has already carried out the test at an earlier time, and thus wishes to set the exercise machine in a manner consistent with his current psycho-physical condition.

In the case of integration into an exercise machine 22, the device 1 may be possibly devoid of means for measuring physical activity, as it is detected directly by the sensors present on the exercise machine 22 itself.

Yet another alternative embodiment of the invention is depicted schematically in figure 11, wherein the device 1, according to any one of the embodiments of figures 1,5,6,7,8, can be removably associated with the exercise machine 22.

For this purpose, a seat 24 in which the user can
insert the device 1 is provided in the exercise machine 22; connection means are provided in the seat, which allow connecting the device 1 to the processing unit of the exercise machine 22.

With this solution, the data stored on the device 1 and the information provided by the processing unit 5 can be displayed and/or managed easily through the user interface 23 of the exercise machine 22, while carrying out an exercise.

In another embodiment of the invention, the device 1 can be associated with the exercise machine 22 even in the absence of a specific seat of insertion of the device 1 itself.

Another embodiment of the invention is depicted schematically in figures 13, 14.

In this embodiment, of particular practical interest, the holder 2 of the device 1 consists of a smartphone, or a mobile phone.

In other entirely equivalent embodiments, the holder 2 may consist, for example, of a tablet or other similar portable medium.

The sensor 4 for detecting the user's heart rate in the predetermined period of time is embedded in a wearable or implantable element 400.

In particular, the wearable or implantable element 400
comprises a band that the user can wear at any time, even during sleep.

In other embodiments of the invention, the wearable or implantable element 400 can consist, for example, of an earpiece: in this case, the user could exploit the advantage of not having to wear other specific devices, but may take advantage of an object that he already uses in everyday life.

The holder 2 comprises a processing unit 5, which is preferably the same processing unit that manages the operation of the smartphone or mobile phone.

An internal memory 6 is also provided for the possible saving of the data collected by the sensor 4 and/or other data of interest, which, in particular, is made up of a portion of the memory already present in the smartphone or mobile phone.

The device 1 also comprises means for detecting the movement of the user 18.

The means for detecting the movement of the user 18 are, for example, of the type described in previous embodiments.

The means for detecting the movement of the user 18 may be, for example, integrated within the holder 2, or integrated within the wearable or implantable element 400, or integrated into either one.
In this way, the user can decide, in various situations, whether to use - to detect his own movement during the predetermined time interval - the wearable or implantable element 400 or the holder 2, or both.

The wearable or implantable element 400 further comprises an on/off button 401, to individually manage its operation.

The on/off button 401 may be provided with a "lock" function to prevent accidental operation.

The wearable or implantable element 400 can also comprise a baseline test start button 402.

For example, with this function the user can carry out a quick test of a few minutes, mostly at rest, to detect the HRV parameter, for example in the morning, or at other particularly significant times of the day.

The wearable or implantable element 400 comprises a respective memory 403 to store the data collected by the heart rate sensor 4 and/or the motion detection sensor 18.

For example, the memory 403 can advantageously be used during sleep to temporarily store the data which will then be transferred to the internal memory 6 of the holder 2.

The memory 403 may be associated with a respective processing unit which locally manages the operation of
the components of the wearable or implantable element 400.

The wearable or implantable element 400 comprises a respective battery 404, for example of rechargeable type.

The wearable or implantable element 400 may also comprise at least one USB port 405 for connection to other devices, both for data transfer and for recharging the battery 404.

It should be noted, however, that all of the functions of the wearable or implantable element 400 can also be controlled remotely via the holder 2 and the connection means 3, for example when the user may not have access to the same because it is under the clothes.

In reference to the embodiment depicted in figure 14, the processing unit 5 of the device 1 is suitable for displaying, in the display 2a of the holder 2, a first indicator 7 of the state of psycho-physical stress of the user.

In particular, the first indicator 7 is displayed in an area 2b of the display 2 - for example a window - especially dedicated to the use of the device 1. The first indicator 7 may be of the type depicted in the description of the preceding embodiments.

Furthermore, the processing unit 5 is suitable for
displaying, in the display 2a, an interface 14 through which the user can enter or manage various data and information related to the operation of the device 1. For example, the interface 14 may include an alphanumeric keyboard for entering data, parameters, etc.

In this embodiment, the display 2a is also suitable for displaying the second indicator 12 for displaying at least one workout program for the user, and/or at least one parameter representative of the intensity of the workout to be carried out, determined according to the method of control and management of the operation of the device described below.

Another embodiment of the device 1 according to the invention is depicted in figure 15. This embodiment differs from those of figures 13, 14 for the fact that the display 2a is suitable for displaying the third indicator 17 for displaying the user's calorie intake during a predetermined time interval, achieving the advantages previously described.

Yet another embodiment of the device 1 according to the invention is depicted in figure 16. This embodiment further differs from that of figure 15 for the fact that the display 2a is suitable for displaying the fourth indicator 19 for displaying the
amount of physical activity of the user during the predetermined time interval, achieving the advantages previously described.

Another object of the present invention is also a method of control and management of the operation of the device 1 according to the present invention. The method according to the invention can also be carried out directly by the processing unit of the exercise machine 22 with which the device 1 is possibly associated.

The method according to the present invention provides for various application modes in relation to the specific situation in which the user is.

Figure 17 is a block diagram which schematically depicts the main operational sequence of the method of control and management of the operation of the device 1, in a situation in which the user is at rest (for example in the morning after waking up).

The first step A of the method - which can be carried out effectively only once at the first use of the device - consists in creating the user's profile.

In this step, the user enters, via the interface 14, information such as gender, age, height and weight, level of usual physical activity, and maybe more.

In the subsequent step B - which in fact usually makes
up the initial step of the method once the user's profile has been created - the resting heart rate of the user is detected via the sensor 4, during a predetermined time interval, for example a few minutes. The collected data are stored in the internal memory 6 of the holder 2 by the processing unit 5.

In the subsequent step C, using the data collected via the sensor 4, the processing unit 5 calculates the user's heart rate variability HRV in such a predetermined time interval, as well as the reserve heart rate according to the Karvonen formula. In particular, through the reserve rate calculated in this way, it is possible to define the aerobic threshold of the user, by correlation with the \( V O_2^{\text{max}} \) parameter (assuming, for example, that the aerobic threshold is around 75% of the user's \( V O_2^{\text{max}} \)).

In the subsequent step D, the processing unit 5 compares the collected heart rate variability HRV datum with the reference values, deemed standard, found in the specialised literature for individuals of a profile similar (for example gender, age) to that of the user. In the subsequent step E, thanks to the information obtained in the previous step D, the processing unit 5 calculates the level of psycho-physical stress of the user related to the above-mentioned predetermined time
interval.
In particular, the level of psycho-physical stress can be determined based on the deviation between the detected and the reference HRV for an individual having that specific profile.

In the subsequent step F of the program, the processing unit 5 generates a workout program for the user, and/or a parameter representative of the intensity of the workout that the user must carry out, based on the level of psycho-physical stress determined in the previous step E and the user's aerobic threshold value determined in the previous step C.

In particular, in this step the processing unit 5 selects, among the many possible types of physical activity pre-set by the user or already present in the internal memory 6 of the holder 2 — for example activities with a prevailing aerobic content such as walking, running, pedalling, etc., or with a prevailing muscular strength development content, such as exercises with weight lifting machines, etc. — those deemed most suitable for the user in relation to his general physical conditions (represented by the aerobic threshold value) and his conditions of psycho-physical stress (represented by the relative level determined through the HRV parameter).
In addition to selecting the most suitable type of physical activity, the processing unit 5 shall also provide, for each specific activity, the recommended intensity, execution time, etc.

In addition to this, in this step the processing unit 5 can also provide the user with further instructions about the execution of other activities which are not actually made up of physical exercises, but which can still be beneficial, such as breathing, walking, mindfulness meditation, stretching, and the like.

As can be understood, the goal for one who practises physical activity is to avoid the risk of overloading the user, in terms of physical effort intensity, if he is in a period wherein his level of psycho-physical stress is deemed high and therefore, in such conditions, physical exercise may not have the desired effect or may even be counterproductive.

For sedentary people, however, the goal is to make them aware of their state of psycho-physical stress and, if necessary, to educate them through instructions, tips and techniques to reduce the level of stress.

Once the workout program and/or a parameter representative of the intensity of the workout that the user must carry out has been generated, in the next step G the processing unit 5 checks whether the
recommended workout has actually been executed. 
If so (step H), the method of management and control terminates.
If not (step I), the processing unit 5 looks after saving the generated program in the internal memory 6, for a possible subsequent use. 
Figure 18 is a block diagram of a further operational sequence of the method of management and control of the device 1 according to the invention.
In particular, the operational sequence schematically represented in figure 18 refers to the execution, on exercise equipment, of the workout program generated in step F of the operational sequence previously described.
The operational sequence according to figure 18 is to be therefore understood as an optional continuation of the main sequence represented in figure 18, should the workout be indeed carried out on exercise equipment. Should the workout be carried out without the aid of exercise equipment, this operational sequence is optional. With reference, then, to such a further optional operational sequence, the program according to the invention comprises a step K of adjusting the functional parameters of the exercise equipment (for
example time, intensity) based on the specific workout program generated in the previous step F.

For example, if the device 1 is associated with the exercise machine 22 as in the embodiment of figure 11, the adjustment of the parameters may be done automatically, through the connection means provided in the seat 24, or through a simple wireless connection between the device 2 and the exercise machine 22.

A step L for initiating the workout program on the exercise equipment then follows.
At the end of the workout, a step M for stopping the exercise equipment follows.

In the subsequent step N, the workout data recorded by the exercise machine are saved in the internal memory 6 of the holder 2 of the device 1, available for future processing.

Figure 19 is a block diagram that refers to a further operational sequence of the method according to the present invention.

In particular, such an operational sequence refers to the possibility of determining the aerobic threshold of the user during the execution of an incremental effort test on exercise equipment.

In particular, the determination of the aerobic threshold is carried out through the detection of the
HRV parameter during the time interval wherein the user carries out the incremental test.

The test can be carried out in a first application situation in which the management method according to the invention can be directly executed by the processing unit of the exercise machine 22, or in a second application situation in which the method is executed by the device 1, which communicates with the exercise machine 22 as previously described.

In a first step 0 of the test, the method provides for the warming (warm-up) of the user. In a subsequent step P, the method determines a variation of the operating parameters of the exercise machine 22 - mainly the intensity of physical exercise - in order to increase the user's effort.

In the subsequent step Q, the method provides for detecting the user's heart rate through the sensor 4; the detection start instant can be non-coincident with the test start instant.

In the subsequent step R, the method provides for an analysis in the frequency domain of the detected signal (LF/HF ratio analysis), thereby determining the HRV parameter and, in particular, its evolution over time within the time interval wherein the test is carried out.
From the knowledge of the evolution over time of the HRV parameter, the aerobic threshold of the user is determined in the subsequent step: in particular, the latter parameter is determined in reference to the typical deflection of the HRV curve depending on the time when the user is under stress (in other words, the decrease of the HRV to below a certain limit allows understanding that the user actually reached the aerobic threshold during the execution of the test).

A block diagram is depicted in figure 20, which refers to yet a further operational sequence of the method of management and control of the device 1 according to the present invention.

More in detail, such an additional operational sequence is related to the detection of the user's behaviour during sleep, in a given predetermined time interval, and to the generation of messages of advice or warning in relation to the detected behaviour.

The operational sequence of the method represented in figure 21 is implemented by using the sensor 4, which must be worn by the user during the entire above-mentioned predetermined time interval.

The data collected by the sensor 4 are saved, by the processing unit 5, in the internal memory of the holder.
The operational sequence of the method represented in figure 21 comprises a first step in which the program detects the user's heart rate, via the sensor 4, during sleep.

In the subsequent step, the method identifies the individual movements of the user during sleep, via the means for detecting the movement of the user (for example, those embedded in the band described in the embodiment of figure 13), to allow distinguishing between wakefulness and sleep.

In the subsequent step, the method determines the HRV parameter, and its evolution over time, based on the heart rate detected in the predetermined time interval. Since the HRV parameter presents specific pattern oscillators that are modulated in relation to the different phases of sleep, REM (Rapid Eye Movement) and NREM (Non-Rapid Eye Movement) sleep is identified in the subsequent step.

The method therefore carries out a qualitative assessment of the user's sleep phases during the above-mentioned predetermined time interval and allows detecting even any sudden reactions of the autonomic nervous system, due, for example, to episodes of sleep apnoea.

In the subsequent step, in relation to the above-
mentioned qualitative assessment of the user's sleep, the method generates messages of advice aimed at improving the behaviours of sleep (for example through techniques of relaxation, of mindfulness meditation, etc.) or of warning in relation to behaviours potentially harmful to the user, such as, for example, episodes of sleep apnoea.

The method of management and control according to the invention therefore allows providing useful information to the user, and monitoring the specified parameters thereof, throughout the day, both during wakefulness and during sleep, both at rest and during the execution of all activities of daily life.

Another object of the present invention is a computer program suitable for carrying out, at least partially, the method previously described.

The computer program, in a preferred embodiment of the invention, is contained in the internal memory 6 of the processing unit 5 of the device 1.

In other embodiments, such a computer program can be contained in a physical medium readable by a computer or the like.

Such a computer may also be embedded in an exercise machine 22 or the like.

The computer program suitable for implementing the
method according to the present invention may be, in other embodiments, installed in a personal computer, in a tablet, in a mobile phone, or the like. Such a program may be, in yet other embodiments, installed in a remote server which the user accesses through an own account by using an own remote connection device.

Yet a further embodiment of the invention is depicted in figure 12, in which the data collected and processed by a device 1 according to the invention, or by a computer on which the computer program runs according to the present invention, are saved on a portable storage medium 25 that can be connected to an exercise machine 22.

In this way - by arranging the processing unit of the exercise machine 22 to read and interpret such data - the method according to the invention can be implemented via the same user interface 23 of the exercise machine, through which the user can receive and manage the information on the workout program and/or on the intensity of the workout to be carried out.

In other embodiments of the invention, any other transfer modes may be provided - for example via any wireless technology - between the computer in which the
computer program runs according to the invention and
the processing unit of the exercise machine 22.
Another object of the present invention is an exercise
machine comprising a processing unit, which manages the
operation of the parts with which the user interacts to
carry out physical activity.
The exercise machine comprises at least one sensor for
detecting the user's heart rate during a predetermined
time interval.
Such a time interval may be the time during which the
user carries out the exercise, or a length of time that
precedes the execution of the exercise.
The sensor for detecting the heart rate can be provided
on the machine, or it can be associated with the same
only during use.
The processing unit comprises means for processing the
data collected by the sensor to determine the heart
rate variability HRV of the user, and hence the
conditions of psycho-physical stress according to the
modes previously described.
Furthermore, the processing unit comprises means for
defining the aerobic threshold of the user based on,
for example, the resting heart rate of the user.
The processing unit also comprises means for generating
at least one workout program for the user, in relation
to the above-mentioned aerobic threshold value and/or one parameter representative of the intensity of the workout that the user must carry out in relation to the above-mentioned aerobic threshold value and in relation to his conditions of psycho-physical stress.

For all the functional details of the processing unit of the exercise machine, refer to the specific description of the monitoring device 1 which also constitutes an object of the present invention.

It has thus been seen how the invention achieves the proposed purposes.

The present invention has been described according to preferred embodiments, but equivalent variants can be conceived without departing from the scope of protection offered by the following claims.
CLAIMS

1. A device for monitoring physiological parameters of a user, comprising
a holder (2) provided with at least one display (2a),
a wearable or implantable element (400) comprising a
sensor 4 for detecting the heart rate (4) of the user
during a predetermined period of time of wakefulness
and/or sleep of the user,
connection means (3) of said holder (2) to said
wearable or implantable element (400),
at least one processing unit (5) of the data detected
by said sensor (4) to determine the heart rate
variability HRV of the user during said predetermined
period of time,
said display (2a) being suitable for displaying at
least one first indicator (7) of the state of psycho-
physical stress of the user, in relation to said
predetermined period of time, understood as a set of
symptoms caused by an imbalance of the Autonomic
Nervous System (ANS),
said state of psycho-physical stress being determined
based on the deviation between the heart rate
variability HRV detected by said sensor (4) and
normative values of reference for the user's profile in
relation to his gender and age,
characterised in that said processing unit (5) is suitable for defining the aerobic threshold of the user and the detected state of psycho-physical stress through the knowledge of the HRV parameter, and for generating at least one workout program for the user and/or one parameter representative of the intensity of the workout that the user must carry out in relation to the determined aerobic threshold value and level of psycho-physical stress.

2. A device according to claim 1, comprising means for detecting the movement of the user (18) embedded in said holder (2) and/or associated with said sensor (4).

3. A device according to claim 2, wherein said processing unit (5) is suitable for generating and displaying on said display (2a) a message related to the user's behaviour detected during sleep, via said sensor (4) and/or said means for detecting the movement (18).

4. A device according to one of the preceding claims, wherein said holder (2) comprises at least one second indicator (12) for displaying at least one workout program for the user, and/or at least one parameter representative of the intensity of the workout that the user must carry out.

5. A device according to the preceding claim,
comprising at least one third indicator (17) for displaying the calorie intake of the user during a predetermined time interval.

6. A device according to one of the preceding claims, comprising at least one interface (14), provided in said holder (2) and/or in said display (2a), through which the user can manage the functions of the device (1) and enter personal information such as his calorie intake during a predetermined time interval, and other specific personal information such as age, gender, weight, height.

7. A device according to claim 5 or 6, wherein said holder (2) comprises at least one fourth indicator (19) for displaying the movement of the user during a predetermined time interval.

8. A device according to one of the preceding claims, wherein said holder (2) consists of a smartphone, a mobile phone, a tablet, or the like.

9. A device according to one of the preceding claims, comprising connection means (20) to other devices such as personal computers, mobile phones, tablets, and the like.

10. A device according to one of the preceding claims, wherein said wearable or implantable element (400) comprises at least one band which embeds said sensor
11. A device according to the preceding claim, wherein said wearable or implantable element (400) comprises an on/off button (401) and/or a baseline test start button (402) and/or at least one USB port (405) for connection to other devices, and/or at least one memory (403) for the storage of the detected data.

12. A device according to claim 10, wherein said means for detecting the movement of the user (18) are embedded in said wearable or implantable element (400).

13. A device according to one of the preceding claims, wherein said processing unit (5) comprises an internal memory (6) for the storage of said workout program and/or of the data detected by said sensor (4) and/or by said means for detecting the movement of the user (18).

14. A method of control and management of the operation of the device (1) according to one of claims 1-13 characterised in that it comprises the steps of:

- detecting the user's heart rate during a predetermined time interval,
- processing the data detected in said step for determining the heart rate variability HRV of the user and therefore his level of psycho-physical stress based on the comparison with normative values of reference...
for the user's profile,
determining the aerobic threshold of the user,
generating at least one workout program for the user in relation to said aerobic threshold value and/or one parameter representative of the intensity of the workout that the user must carry out in relation to said aerobic threshold value and in relation to said level of psycho-physical stress.

15. A method according to claim 14, wherein said step of determining the aerobic threshold of the user is carried out from the determination of the resting heart rate.

16. A method according to one of claims 14,15, wherein said step of determining the level of psycho-physical stress of the user is carried out based on the comparison between the detected HRV parameter and the reference one for users of a similar profile for age and gender.

17. A method according to one of claims 14-16, further comprising a step of determining the aerobic threshold of the user during the execution of an incremental effort test on exercise equipment based on the HRV parameter detected during the test and based on an analysis in the domain of frequencies, and/or of time and/or of time-frequencies of said HRV parameter
detected during the test.

18. A method according to one of claims 14-17, comprising a step of detecting the movement of the user during said predetermined time interval during the user's sleep.

19. A method according to claim 18, further comprising the step of carrying out a qualitative assessment of the user's sleep at least based on the analysis of the detected HRV parameter and based on the user's movements detected during said predetermined period.

20. A computer program, suitable for carrying out, at least partially, the method according to one of claims 14-19.

21. A computer program according to the preceding claim, contained in a physical medium readable by a computer or the like.

22. A computer program according to one of claims 20, 21, contained in the memory of the computer of an exercise machine (22) or the like.

23. An exercise machine (22), comprising a device (1) for monitoring physiological parameters of a user according to one of claims 1-13, or comprising a processing unit comprising the computer program according to one of claims 20-22.

24. An exercise machine, comprising a seat (24) for
the insertion of a monitoring device (1) according to one of claims 1-13, connection means being provided in said seat (24) that allow connecting said device (1) to the processing unit of the exercise machine.

25. An exercise machine, comprising a processing unit and at least one sensor (4) for detecting the heart rate of a user during a predetermined time interval, characterised in that said processing unit comprises means for processing the data detected by said sensor to determine the heart rate variability HRV of the user and the level of psycho-physical stress of the user.

26. An exercise machine according to claim 25, wherein said processing unit comprises means for defining the aerobic threshold of the user.

27. An exercise machine according to claim 26, wherein said processing unit comprises means for generating at least one workout program for the user in relation to said aerobic threshold value and/or one parameter representative of the intensity of the workout that the user must carry out in relation to said aerobic threshold value and in relation to said level of psycho-physical stress.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/Q24 A63B24/0Q A61B5/22

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)
A61B A63B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
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<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
  *A* document defining the general state of the art which is not considered to be of particular relevance
  *E* earlier application or patent but published on or after the international filing date
  *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  *O* document referring to oral disclosure, use, exhibition or other means
  *P* document published prior to the international filing date but later than the priority date claimed
  *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  *K* document member of the same patent family

Date of the actual completion of the international search: 22 January 2015
Date of mailing of the international search report: 02/02/2015

Name and mailing address of the ISA/ European Patent Office, P.B. 5018 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer: Schindler, Martin
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INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 14 - 19
   because they relate to subject matter not required to be searched by this Authority, namely:
   see FURTHER INFORMATION sheet PCT/ISA/2 10

2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. All required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

- The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

- No protest accompanied the payment of additional search fees.
Claims 14 to 19 refer to a method comprising the method step of generating a training program representative of the intensity of the workout. As this training program has therapeutic effects, e.g. improvement of the cardiovascular system of a patient and reduction caused by an imbalance of the Autonomic Nervous System (ANS), the method qualifies as treatment of the human or animal body by therapy and is therefore not allowable according to Rule 39.1(iv) PCT.
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