

## EUROPEAN QUALIFYING EXAMINATION 2017

# Paper B

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## **Description of the Application**

[01] The present application relates to monitoring at least one vital sign of the human body by optical means. The four vital signs, pulse, body temperature, blood pressure and blood oxygen saturation, have to be monitored regularly for controlling the medical status of a patient in hospital. Monitoring vital signs at home will play a more and more important role in remote medicine. D1 discloses monitoring vital signs by attaching sensors to the human body with a clip. This has the drawback that the clip is uncomfortable and that for long-term measurements the attachment is not reliable, because the clip can move. Therefore, the aim of this invention is to provide a reliable and comfortable system for long-term remote monitoring of the vital signs of patients, such as small children and babies.

[02] The invention concerns a system comprising means for attaching an optical sensor and a motion sensor to the human body. The attaching means comprises means for transmitting output signals from the sensors to an evaluation means for calculating at least one vital sign from the output signals. The inventive idea is that the attaching means is a garment, such as a sock or a wristband, and that the evaluation means is configured to correct the output signal from the optical sensor based on the output signal of the motion sensor, and vice-versa. It is not important for the invention how the signals are transmitted to the evaluation means.

[03] Figs. 1-3 show systems according to first, second and third embodiments of the invention. The invention will be described below with reference to the drawings.

[04] Fig. 1 shows a system for remotely monitoring vital signs. The system comprises a sock 1 for attaching an optical sensor 2 and a motion sensor 3 to a human body 10. The sock 1 comprises transmitting means 4 for transmitting the output signals of sensors 2 and 3 to evaluation means 5. The transmitting means 4 may be any kind of transmitting means, such as a serial port for a cable, or wireless transmitting means, such as a wireless local network emitter.



[05] The evaluation means 5 is configured to receive and process the transmitted signals and may be a computer, a software application called App, or a smart phone, such as a *iPhone*. The vital signs are calculated from the output signals of the sensors and may be outputted as an audio signal or displayed on a screen 6 of the evaluation means 5.

[06] The optical sensor 2 comprises a light source 2a and a light detector 2b. The light source 2a emits a light beam 7a towards the human body 10 and the light detector 2b measures the light 7b having passed through the human body, i.e. not absorbed by the human body. 2a and 2b are part of an optical pulse oximeter as described in D1.

[07] Accommodating an optical sensor into a garment adds electrical noise to the output signal of the optical sensor 2. A sock 1 worn by a baby moves frequently, which adds further noise to the output signal from the optical sensor 2. This further reduces the quality of the output signal. In order to overcome this drawback, in the first embodiment, the motion sensor 3 is placed next to, preferably between, the light source 2a and the light detector 2b. However, motion sensor 3, light source 2a and light detector 2b may be placed at any position in the garment 1. The relative position of these components to each other is not important. The output signal of the motion sensor 3 is also transmitted by the transmitting means 4 to the evaluation means 5.

[08] In the evaluation means 5 the output signal from the optical sensor 2 is corrected based on the output signal from the motion sensor 3 such that noise is reduced. This leads to better signal quality, thereby preventing false measurements.

Example for correcting the signal: A quick movement of the foot causes an erroneous peak to occur in the output signal of the optical sensor 2 and simultaneously, a peak in the output signal of the motion sensor 3. The evaluation means 5 uses the output signal from the motion sensor 3 to remove the erroneous peak in the output signal of the optical sensor 2. Vice versa the output signal from the motion sensor 3, which may be used for directly measuring a patient's pulse, may be corrected by the output signal of sensor 2. The relative position of the motion sensor 3 with respect to the optical sensor 2 is not important for correcting the signals.



[09] The evaluation means 5 is configured to calculate from the corrected signals the vital signs as is described in more detail in D1. The sock 1 may be replaced by a wristband 11 as shown in Fig. 2. However, any garment may be used. The garment may be at least partially made of *Optitex*<sup>™</sup>, which is a material comprising 50-60% cotton, 30-40% polyurethane and 10-20% polyethylene glycol in % by weight. The remaining technical features, such as the transmitting means 14, light source 12a, light detector 12b and motion sensor 13, are identical to the first embodiment.

[10] Fig. 3 shows a system for use while doing sport such as running or cycling. The system comprises a headband 21 for goggles 20. The goggles 20 protect the eyes from foreign objects and water. The optical sensor 22, i.e. light source 22a and light detector 22b, and the motion sensor 23 are attached to the ear 27 by means of the headband 21. The headband 21 is a garment and may be made of *Optitex*<sup>™</sup> which provides reliable, secure and comfortable attachment of the sensors to the ear.

[11] Accordingly, Fig. 3 shows a system for monitoring the vital signs of the human body, the system comprising the headband 21 for attaching the optical sensor 22 and the motion sensor 23 to the human body. The headband 21 comprises, in addition to the sensors 22 and 23, transmitting means 24 for transmitting the output signals from the sensors. The system further comprises an evaluation means 25 for receiving the output signals and calculating therefrom at least one of the vital signs. The evaluation means 25 is configured to correct the output signal from the sensor 22 based on the output signal of sensor 23, and vice-versa.

[12] In this embodiment it is essential that the vital signs are not displayed on the screen of the evaluation means 25, because the screen is used for other purposes, such as displaying a map. Instead the vital signs may be output as an audio signal, e.g. to an earphone 26 attached to the headband 21. The transmitting means 24 may be a wireless transmitting means or any other kind of transmitting means, such as described for the other embodiments.

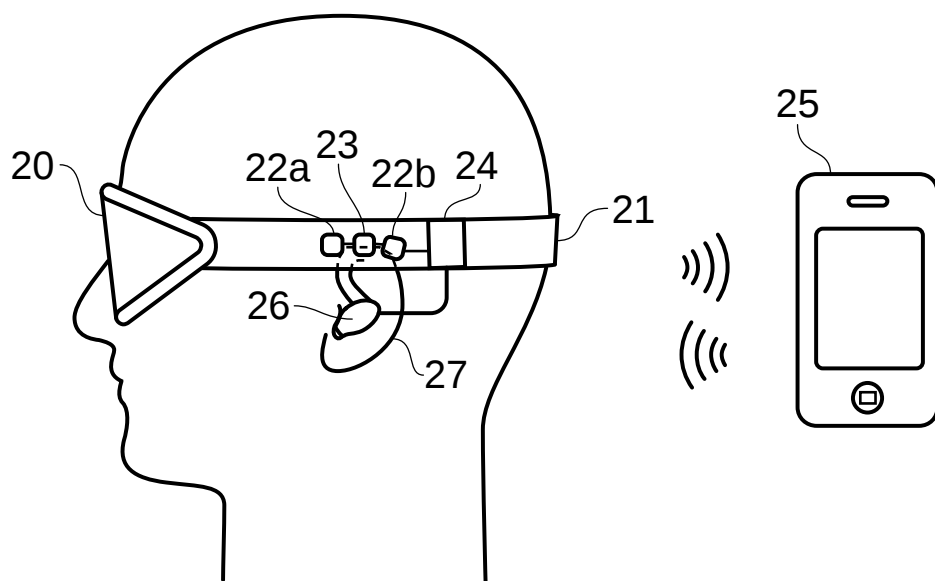
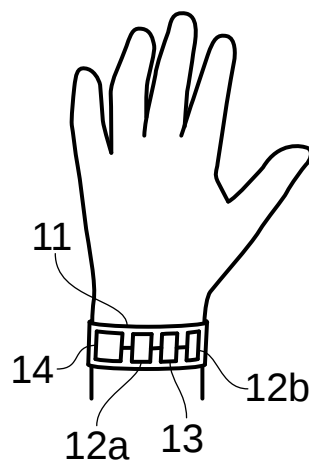
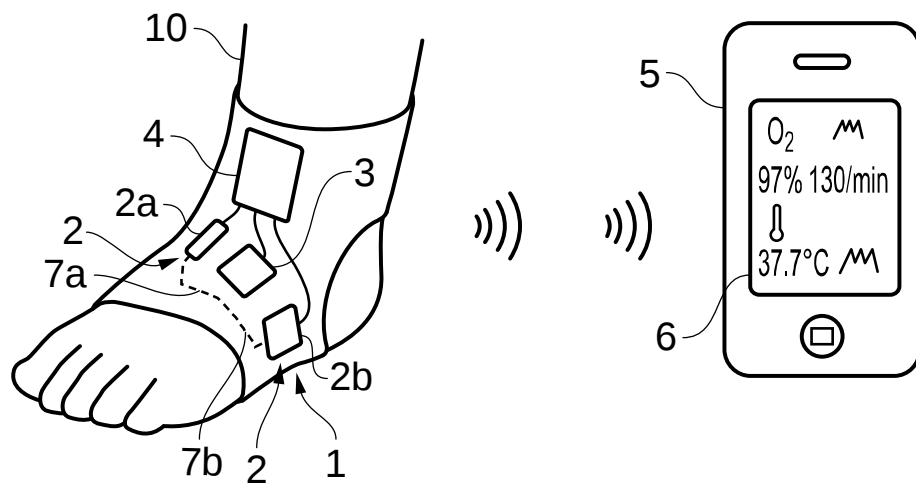


## Claims

1. System for monitoring at least one vital sign of a human body, the system comprising:
  - holding means (1, 11, 21) for holding an optical sensor (2, 12, 22) and a motion sensor (3, 13, 23) close to the human body (10, 27), the holding means (1, 11, 21) comprising in addition to the sensors (2, 12, 22, 3, 13, 23) transmitting means (4, 14, 24) for transmitting output signals from the sensors (2, 12, 22, 3, 13, 23),
  - evaluation means (5, 25) for receiving the output signals and calculating from the output signals the at least one vital sign,characterised in that the evaluation means (5, 25) is configured to correct the output signal from the optical sensor (2, 12, 22) based on the output signal of the motion sensor (3, 13, 23) or to correct the output signal from the motion sensor (3, 13, 23) based on the output signal of the optical sensor and in that the transmitting means (4, 14, 24) is a wireless transmitting means.
2. System according to claim 1, wherein the at least one vital sign is pulse, body temperature, blood pressure and/or blood oxygen saturation.
3. System according to claim 1 or 2, wherein the wireless transmitting means (4, 14, 24) is a wireless local network emitter.
4. System according to any of claims 1 to 3, further comprising a screen (6) and configured to display the at least one vital sign on the screen.
5. System according to any of claims 1 to 4, wherein the holding means is an attaching means (1, 11, 21) such as a sock (1), a wristband (11) or a glove.
6. System according to any of claims 1 to 5, wherein the attaching means (1, 11, 21) is at least partly made of *Optitex*<sup>™</sup>.



Drawings of the Application



## **Communication**

1. The examination is based on the application as originally filed. Documents D1-D3 are prior art according to **Art. 54(2) EPC**.

### **2. Art. 54(1) and (2) EPC (Novelty)**

The subject-matter of **claims 1-4** is *not novel* within the meaning of **Art. 54(1) and (2) EPC**, because it is known from D2:

2.1 Claim 1: D2 discloses in paragraph [01] a system for monitoring at least one vital sign of a human body, the system comprising holding means (support for the camera (2), cf. par. [01]) for holding an optical sensor (camera sensor) and a motion sensor (motion sensor in the camera) “close” to the human body (cf. point 3.1 below), the holding means comprising a transmitting means for transmitting output signals from the sensors to evaluation means (smart phone), the evaluation means being configured to correct the output signal from the optical sensor based on the output signal of the motion sensor (SMOOTHY App, cf. par. [02]). The evaluation means calculates a vital sign (pulse, cf. par. [01]). The transmitting means is a wireless transmitting means (cf. par. [02]).

2.2 Claim 2: D2 further discloses in par. [01] measuring the pulse.

2.3 Claim 3: D2 further discloses in par. [02] a wireless local network emitter.

2.4 Claim 4: D2 further discloses in par. [01] as display means a screen.

### **3. Art. 84 EPC (Clarity)**

3.1 Claim 1: The expression “[holding] ... **close** to the human body” is a relative term and thus unclear. An unclear term cannot be used by the applicant to distinguish the invention from the prior art (Guidelines F-IV, 4.6).



- 3.2 Claim 5: The technical feature “**glove**” is **only mentioned in the claims and not in the description**. According to **Art. 84 EPC** it is required that the **claims are supported by the description**.
- 3.3 Claim 6: Optitex™ is a **Trademark**. The definition of a composition by a trademark may change and therefore is unclear under **Art. 84 EPC** (cf. Guidelines F-IV, 4.8).
4. If the applicant wishes to maintain the application, **new claims** should be filed which take the above objections into account.
5. Care should further be taken that the **dependency** of the amended **dependent claims** is correct.
6. In order to facilitate the examination as to whether the new claims contain subject-matter which extends beyond the content of the application as originally filed, the applicant is requested to indicate precisely where in the application documents any **amendments** proposed find a **basis (Art. 123(2) EPC and Rule 137(4) EPC)**. **This also applies to the deletion of features**.
7. Care should be taken to ensure that the new claims comply with the requirements of the EPC in respect of **clarity, novelty, inventive step** and, if relevant, **unity (Art. 84, 54, 56 and 82 EPC)**.
8. In the letter of reply, the **problem and solution approach** should be followed. In particular, the **difference between the independent claim and the prior art (D1-D3)** should be indicated. The **technical problem** underlying the invention in view of the **closest prior art** and the **solution** to this problem should be readily derivable from the reply of the applicant.



**Document D1: From text book “Medical Technology”**

**[01]** Described is an optical pulse oximeter for measuring the pulse and the oxygen saturation in the blood.

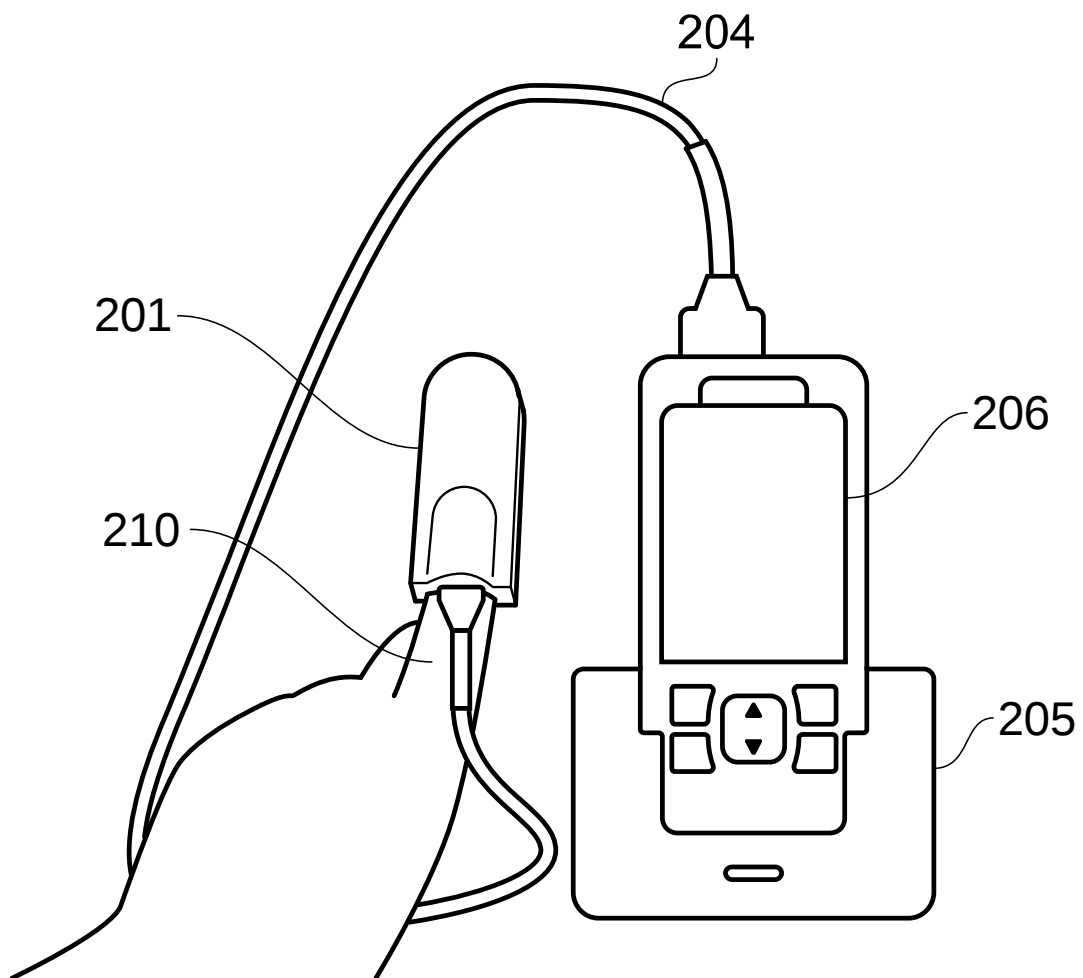
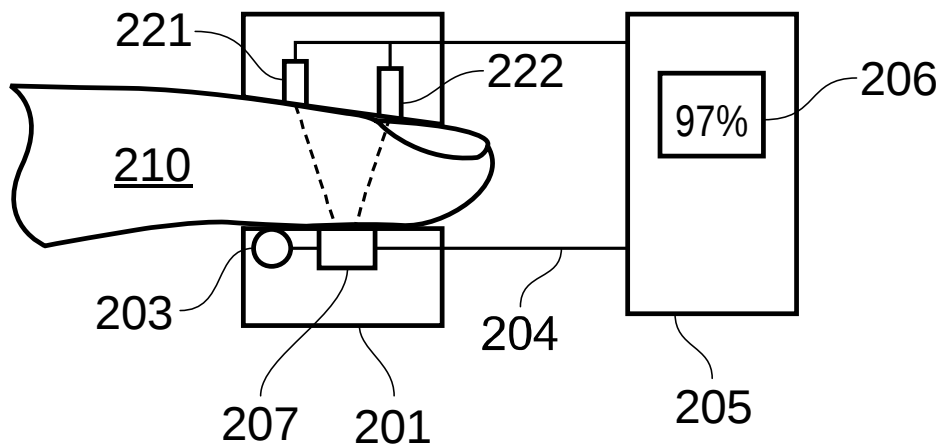
**[02]** As shown in the figures the optical pulse oximeter typically utilizes a first LED (light-emitting diode) 221 and a second LED 222 facing an optical sensor 207 on both sides of a part of a patient's body, usually a fingertip or an earlobe. The first LED 221 emits red light and the second LED 222 emits infrared light. Absorption of light at these wavelengths differs significantly between blood loaded with oxygen and blood lacking oxygen. Oxygenated haemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated haemoglobin allows more infrared light to pass through and absorbs more red light. The LEDs flash about thirty times per second.

**[03]** The optical sensor 207 measures the intensity of the light that passes through, i.e. is not absorbed. The measurement fluctuates in time because the amount of arterial blood pulses with the heartbeat frequency. An evaluation means 205 calculates the oxygen saturation in the blood as well as the pulse from the ratio of the red light measurement to the infrared light measurement. The intensity of the infrared signal measured by the optical sensor 207 is proportional to the body temperature. From the blood oxygen saturation, pulse and body temperature, the blood pressure can be calculated. The calculated values are displayed on screen 206.

**[04]** The LEDs 221, 222 and the optical sensor 207 are integrated into a clip 201 which is attached to a finger 210. The clip 201 is connected to the evaluation means 205 by means of a cable 204. In order to achieve better accuracy and reliability of the pulse measurement, the pulse can be measured independently from the optical pulse oximeter by means of a sensor 203, such as a pressure sensor or a motion sensor, which could also be integrated into the clip. Preferably a pressure sensor is used, because a motion sensor, which is reliable enough to measure the pulse, is typically large and heavy and therefore uncomfortable for the patient. The evaluation means 205 comprises simple, but fast software. This allows quick signal processing, but no further software can be installed in the evaluation means 205.



Drawings Document D1



**Document D2: Advertisement from the magazine “Smart phone & Co”**

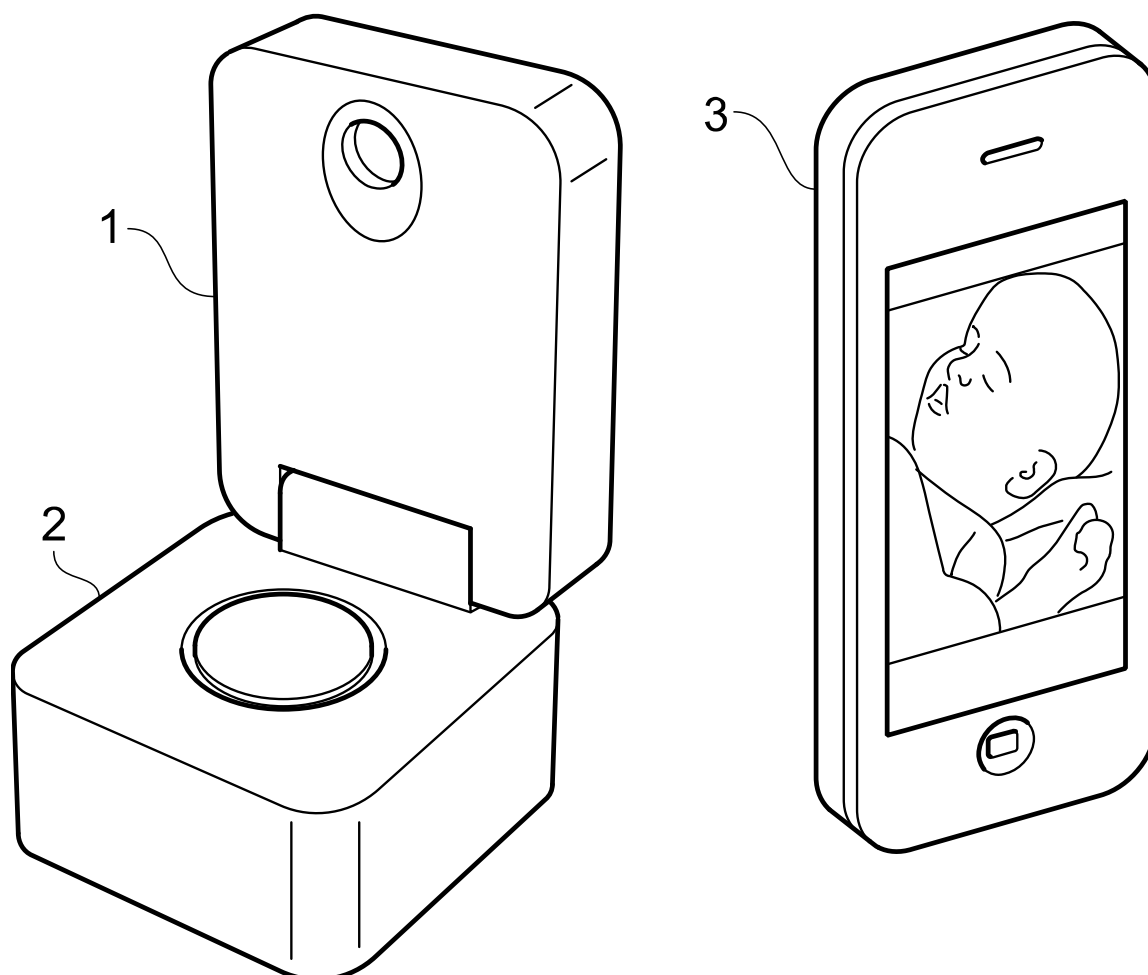
[01] Now there is the latest gadget for your *jPhone*: a *jPhone* babyphone! With the *Wittings Smart Baby Monitor WSBW 4.0* you don't just simply monitor your child (also at night, thanks to a built-in infra-red image sensor), but you can directly interact with your child, e.g. by sending soothing music. Even better, the *WSBW 4.0* not only transmits sound and images, but also monitors the current room temperature and the relative humidity of the air. The camera 1 detects small changes in the colour of the skin to measure the pulse of your baby and to display the pulse on a screen. The camera is mounted on a support 2 holding the camera close to the baby, but out of reach of the baby such that the camera cannot be damaged. The camera is movable about two axes. The infra-red sensor is used to automatically adjust the position of the camera 1 when your baby moves.

[02] The *Wittings Smart Baby Monitor* exchanges all data with your smart phone via wireless local network or any other wireless connection. Many *jPhone* apps are available for the *WSBW 4.0*. The *SMOOTHY* App installed in your *jPhone* 3 determines the motion of the camera 1 using a motion sensor in the camera. The *SMOOTHY* App corrects the sound and image signals from the camera on the basis of the motion data from the motion sensor in the camera, thereby reducing undesired noise from the signals. This achieves even better sound and picture quality.

[03] The *Wittings Smart Baby Monitor* is available for 130 Euros from October 2014 at [www.arctic.com](http://www.arctic.com). *SMOOTHY* App: 1 Euro.



Drawing Document D2



**Document D3: Technical Disclosure from “Brooker, Phils & Siems”**

[01] Disclosed is a sock, comprising an electrical sensor for electrocardiography. Electrocardiography is the recording of the electrical activity of the heart. The electrical activity of the heart is detected by electrical sensors in contact with the skin of a human body.

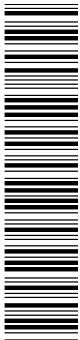
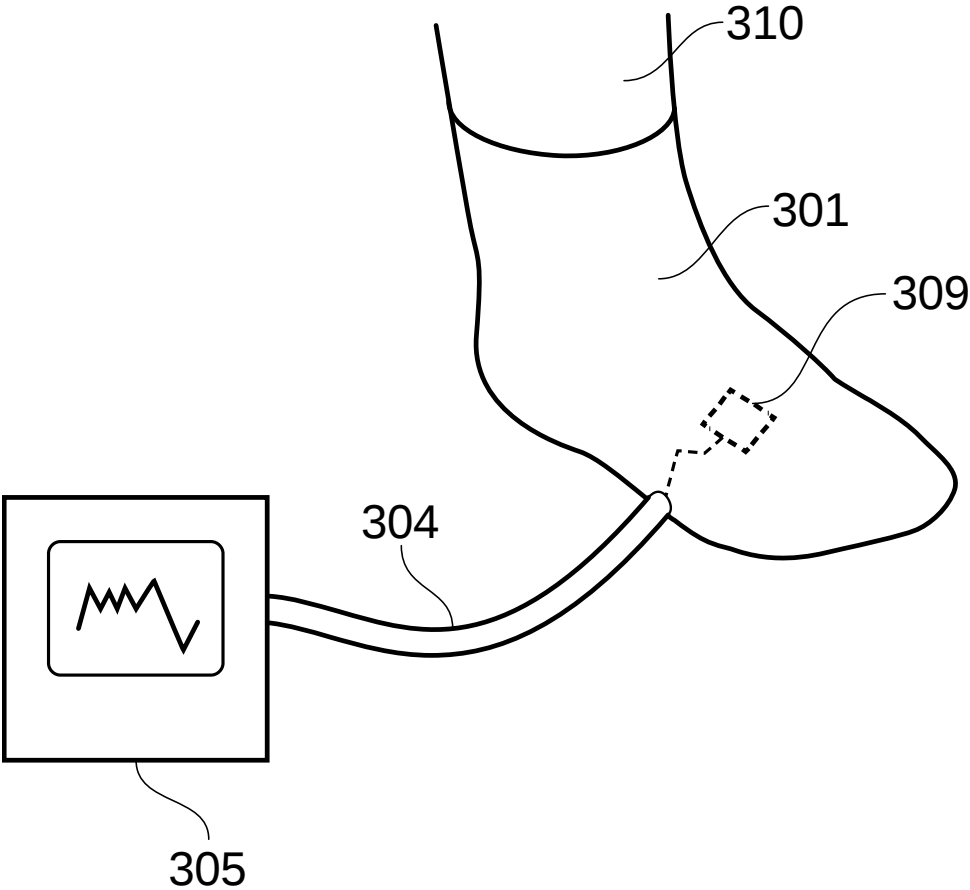
[02] The figure shows a sock 301 comprising an electrical sensor 309 and a cable 304 that can be connected to an evaluation means 305 for processing the data from the sensor. The sock 301 is pulled over a patient's foot 310 such that the electrical sensor is in contact with the foot. The electrical signal from the electrical sensor 309 is evaluated and displayed by the evaluation means 305.

[03] The sock 301 is a reliable, secure and comfortable means for attaching the electrical sensor 309 to the human body. The sock 301 is at least partially made of a material comprising 50-60% cotton, 30-40% polyurethane and 10-20% polyethylene - glycol in % by weight. This material unfortunately allows measurements only with electrical sensors, because for any other type of sensor, e.g. optical sensor, the signal to noise ratio would be too low for measuring vital signs of the human body. Therefore, this material is not suitable for recording vital signs.

[04] Instead of a sock another kind of garment may be used, such as a glove, a wristband or a headband. A glove in particular is a reliable and comfortable means for attaching sensors to the human body.



Drawing Document D3



Dear Ms. Evita Lee-Tea,

**[01]** Our invention has the advantage that the vital signs can be remotely monitored with a reliable, secure and comfortable attachment of the sensors in combination with a high signal quality, which is achieved by noise reduction through correcting the sensor output signals.

**[02]** We propose filing the enclosed draft set of claims together with your reply to the official communication. We are convinced that the subject-matter of amended claim 1 is novel and inventive. Please make any amendments to the proposed set of claims you consider to be necessary for the claims to fulfil the requirements of the EPC, whilst giving us the broadest possible scope of protection for our invention.

**[03]** Claim 1 has been restricted by including the features of dependent claim 5. Claim 1 is drafted in the two-part form with respect to D1, because D2 and D3 are from remote technical fields. We have moved the wireless transmission from claim 1 to amended dependent claim 2, because for some applications this kind of transmission is not suitable. We do not want to have a dependent claim related to the subject matter of original claim 2. We only want to protect a system, where the attaching means is (any kind of) a garment. Please amend the claims accordingly, if possible.

**[04]** The third embodiment is enjoying unexpected success in the sports article market. To cover this embodiment, we replaced the erroneous word “glove” in amended claim 1 by “headband for goggles”. It is very important for us to have protection for this embodiment. Inspired by the erroneous word “glove” and by the teaching of D3 we intend to produce a glove comprising optical and motion sensors according to our inventive idea. If possible, please protect the option that the garment is a glove. In view of the comment of the examiner in section 3.2 you may have to provide corresponding reasoning. Otherwise we do not want you to add further dependent claims.

Regards

B. Aby

Enclosure: Draft set of claims



1. System for monitoring at least one vital sign of a human body, the system comprising:

- ~~holding~~ attaching means (1, 11, 21) for ~~holding~~ attaching an optical sensor (2, 12, 22) and a motion sensor (3, 13, 23) ~~close~~ to the human body (10, 27), the ~~holding~~ attaching means (1, 11, 21) comprising in addition to the sensors (2, 12, 22, 3, 13, 23) transmitting means (4, 14, 24) for transmitting output signals from the sensors (2, 12, 22, 3, 13, 23),
- evaluation means (5, 25) for receiving the output signals and calculating from the output signals the at least one vital sign,

characterised in that the attaching means (1, 11, 21) is one of a sock (1), a wristband (11) or a headband (21) for goggles (20)  
and in that the evaluation means (5, 25) is configured to correct the output signal from the optical sensor (2, 12, 22) based on the output signal of the motion sensor (3, 13, 23) or to correct the output signal from the motion sensor (3, 13, 23) based on the output signal of the optical sensor  
~~and wherein the transmitting means is a wireless transmitting means (4, 14, 24).~~

2. System according to claim 1, wherein the ~~at least one vital sign is pulse, body temperature, blood pressure and/or blood oxygen saturation~~ output signals are transmitted by wireless transmitting means (4, 14, 24).

3. System according to claim 1 or 2, wherein the wireless transmitting means (4, 14, 24) is a wireless local network emitter.

4. System according to any of claims 1 to 3, further comprising a screen (6) and configured to display the at least one vital sign on the screen.

~~5. System according to any of claims 1 to 4, wherein the holding means is an attaching means such as a sock (1), a wristband (11) or a glove.~~

5. ~~6.~~ System according to any of claims 1 to ~~5~~ 4, wherein the attaching means (1, 11, 21) is at least partly made of *Optitex*<sup>™</sup>.

