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(54) **Title:** A DEVICE FOR MEASURING STRABISMUS AND ASSESSING OCULAR MOVEMENT

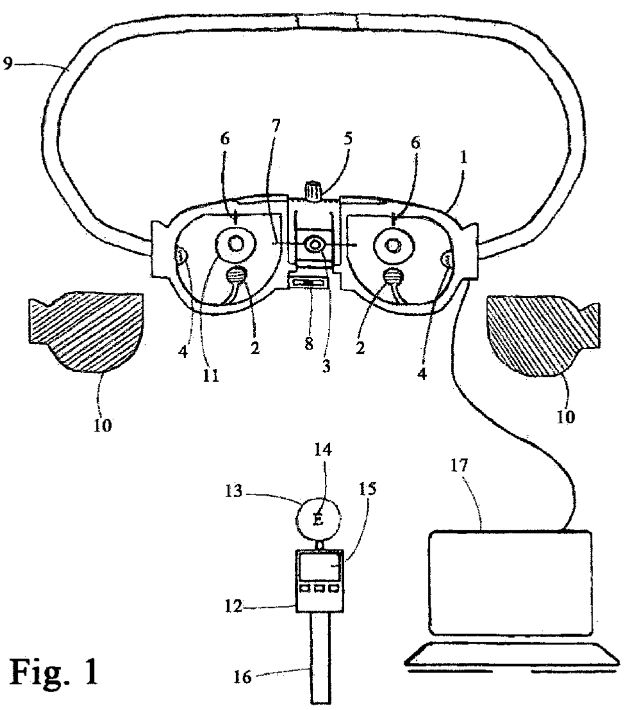

Fig. 1

(57) **Abstract:** The disclosure is a device for measuring strabismus and assessing ocular movement via three cameras (2, 3) that are fixated on a frame (1) which will be worn by the patient and which resembles the frame of normal spectacles. Two internal cameras (2) will photograph patient's eye while the third external camera (3) will photograph a special fixation target (14) that will be moved in different directions by the examiner. There is also a computer (17) that will receive and analyze the images which will come from the three cameras (2, 3) simultaneously.

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[Continued on next page]

Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report (Art. 21(3))*

Title of the invention:

A device for measuring strabismus and assessing ocular movement

Background of the invention:

Squint (or strabismus) is a very common disease that affects perhaps 2% of people, and it has many types, and moreover, a much higher percentage of people may have a latent strabismus, which is called "phoria", which may cause visual stress and difficulties in visual activities. Measuring the angle of squint (or phoria) in the different positions of gaze is one of the important challenges for ophthalmologists, and it carries many difficulties and many potential sources of errors. It also requires a considerable time and in the same time it is very important to diagnose and treat every case.

There are some attempts to develop a device that measures the angle of strabismus by imaging the eyes and analyzing images by a special software, but the vast majority of ophthalmologists were not convinced by these devices and still rely on the traditional measurement using prisms and alternate cover test, which is the method that has been used for decades.

In order to get accurate strabismus measurements from analyzing the images of the two eyes in the different positions of gaze, the position of the target that the eyes are looking at must be precisely defined during imaging (a change of one degree centigrade, either horizontally or vertically, constitutes a source of error). Also the attempt to calculate the angle between the two eyes by analyzing the picture carries a large room for error due to what is known as the kappa angle, which is the angle between the optical axis and the anatomical axis of the eye, and also because of the possibility of difference between the two eyes in size and dimensions.

Brief description of the drawing:

Fig 1: The whole components of the device

Detailed Description of the Invention:

The invention is a device for accurate measuring of strabismus or phoria angle in all positions of gaze and from any desired viewing distance, and it also gives an accurate assessment of ocular movement. The device, as shown in Figure 1, consists of a frame (1) that is similar to the frame of normal glasses, but it is fixed on the face by a belt (9) that is flexible or has an adjustable length. The frame should be wide enough for allowing a wide field of vision and also for allowing to wear it over the patient`s glasses (if he wears glasses). There should also be a screw (5) for changing the width of the frame, and a vertical indicator (6) on each side so that the screw (5) can be rotated until each vertical indicator is at the level of the middle of the patient's eye (11), the device also contains three cameras, two side cameras (2) we will call them the two “internal cameras” because they point towards the patient’s eyes, and each one of them will photograph one of the patient’s eyes, and they will be fixed on the frame from below, and a single camera (3) which is positioned centrally in the middle of the frame, we will call it the “external camera” because it will photograph the target that the patient is looking at, this external camera is installed on a vertical rail so it can be raised or lowered, and it is equipped with a horizontal pointer (7) that must correspond to the middle of the pupil horizontally, there is also a bubble level (8) to adjust the horizontal position of the frame so that both internal cameras are completely at the same horizontal level when the head is strait, and two opaque covers (10) each one of them for one side of the frame openings and it can be fixed and removed by a magnet method or by any other method. The two internal cameras must have the ability to photograph from a very close distance and also in dark conditions when placing the opaque cover so they must have the feature of infrared imaging, thus, the frame must be equipped with an infrared lamp (4) on each side, and the frame must be wired to a computer (17) that receives and analyzes the images coming from the three cameras and provides, through the same connection the electrical energy required for the work of the cameras and the infrared lamps. The device also contains a moving part (12) which is separate from the frame and represents the holder of the target that the patient will look at. The moving part in turn contains a ball (13) which is fixed on it from the top, we will call it the "colored ball" because it will take a distinctive color so that the computer can easily recognize it from the pictures and videos taken by the external camera. The fixation target (14) that the patient should look is drawn in the middle of the ball1s surface, there can also be a special target for adults (which is usually an alphabetical letter) and another target for children (cartoon image) and the two targets are located on opposite sides of the ball which can be rotated around the vertical axis on which it is fixed, so that the appropriate target is facing the face of the patient, the moving part also contains a small screen (15) that will display digital indicators that are received wirelessly from the computer, and also a handle (16) that allows the examiner to hold and move the moving part during the test.

The device`s principle of works is the simultaneous imaging of the eyes and the fixation target at the same time, so that the computer will be able to accurately determine the position of the fixation target in relation to the external camera (and thus to the patient`s eyes) from analyzing the image of the camera, and the target distance will be calculated by measuring the diameter of the colored ball in the picture and comparing it to its real diameter, the farther away the ball is from the camera, the smaller its diameter will be in the picture, and the angle of its deviation from the camera`s level can be determined both horizontally and vertically.

The test must first be carried out by placing the opaque cover over one of the eyes which we will call the “non-fixating eye”. The examiner holds the moving part of the device from the required examination distance and the patient must fixate with his open eye (which we will call the “fixating eye”) on the fixation target which is on the colored ball, while the examiner moves the target in different directions of view (Right, left, top, bottom, and oblique directions). During this, the external camera will photograph the fixation target and locate it precisely in every fraction of a second during its movement, and at the same time the two internal cameras will photograph both eyes (the non-fixating eye will be photographed with the help of the infrared light). Then a special software will relate every location of the fixation target to the image of the fixating eye at that moment, and the unavailable images will be programmatically completed with the help of artificial intelligence so that the software will predict the presumed image of the fixation eye for every position of the fixation target in the space, in other words, the software will be able to determine the image of the eye and its very accurate position when it looks at any direction in the space, if the software couldn`t complete the whole images programmatically it may request re-examination at certain angles in order to complete the task accurately. Regarding to the non-fixation eye, its captured images will be saved in all the positions in which the target had moved, and then the test must be repeated again, but after changing the coverage between the eyes. And consequently, the software will contain pictures of each eye when it looks at any angle in the space (some are real images and some are drawn with the help of artificial intelligence) and pictures of each eye when it was covered while the other eye was looking in the directions in which the target had moved during the test. Thus, it will be possible to measure the angle of strabismus or phoria at any angle in which the fixation target was, this will be done not by comparing the images of the two eyes (because that may carry many errors), but by comparing the images of the eye when it was the non-fixation eye by the images of the same eye when it was the fixation eye, and this will allow us to get very accurate measurements of strabismus in all positions of gaze and from any examination distance we want, thus excluding most sources of error, especially those related to the difference in the size of the eyes and the angle kappa (the angle between the optical axis and the anatomical axis of the eye), and also the examination will be done in a natural environment that uses a normal accommodative target of fixation and it does not cause any disturbance in the patient's sense of the distance of the target, which may affect the result of the examination.

Through video imaging of the eyes and image processing, the device can also detect and assess other eye movement disorders such as nystagmus and movement limitation…, and it will also grant ophthalmologists a unique opportunity for monitoring and recording eye movement in an excellent way while it is under the cover and while the other eye is following a specific target that moves in certain directions, with accurate numeric determination of the target position and of the horizontal and vertical angles in which the covered eye is deviated from the correct position at every moment, this was not previously available by any way.

In addition to the above, the computer will wirelessly send to the moving part information about the distance of the fixation target and its position in the space, horizontally and vertically regarding to the external camera, and this information will be displayed numerically on the screen of the moving part (15), this will help the examiner to move the fixation target thoughtfully, especially if the software couldn`t obtain sufficient images of the eyes and asked the examiner to repeat the test at certain angles. The computer will be able to locate the colored ball easily within the images of the external camera through its distinctive color and its projection which will be a circle whatever was its angle with the camera.

Also, after performing the two stages of the test by covering one eye in each stage, a third stage can be performed by opening both eyes, this stage will give information about the possible control on strabismus in some or all positions of gaze.

One of the additions that may improve the device is to replace the opaque cover (10) by covering both sides of the frame with a smart glass, which turns from opaque to transparent and vice versa when a certain electrical current passes through it, and thus it will be possible to control the coverage of both eyes automatically through the computer without getting close to the patient and without any mechanical movements that may disturb him if he was a child.

What is claimed is:

1. A device for measuring strabismus and assessing ocular movement that consists of a frame similar to the frame of normal glasses ,this frame will be worn by the patient and fixed on his head with a belt. There are three cameras that are fixated on the frame, two of them are dedicated to photographing the two eyes from a close distance (each camera for one eye) with the possibility of infrared imaging in darkness, and a third camera in the middle of the frame which is dedicated for photographing the target that the patient looks at simultaneously with the imaging of the eyes by the previous two cameras, and also an opaque cover on each side of the frame which can be attached and removed. The frame must be connected to a computer that will receive and analyse the images from the three cameras. The device also contains a moving part which is separated from the frame, this moving part contains a handle that must be held by the examiner, and a colored ball which has a distinctive color so that the computer can easily distinguish it in the image of the camera, and on the ball there is a picture which is the target of fixation that the patient will look at while the examiner moves the moving part in different directions .
2. A device for measuring strabismus and assessing ocular movement as described in claim 1 that its moving part contains an electronic screen for displaying the examination distance and the vertical and horizontal angles at which the target of fixation deviates, this information will reach the screen wirelessly from the computer.
3. A device for measuring strabismus and assessing ocular movement as described in claim 1 but the frame is covered with smart glass, so that

each eye can be covered or uncovered automatically by passing an electric current through the glass instead of using the removable opaque cover.

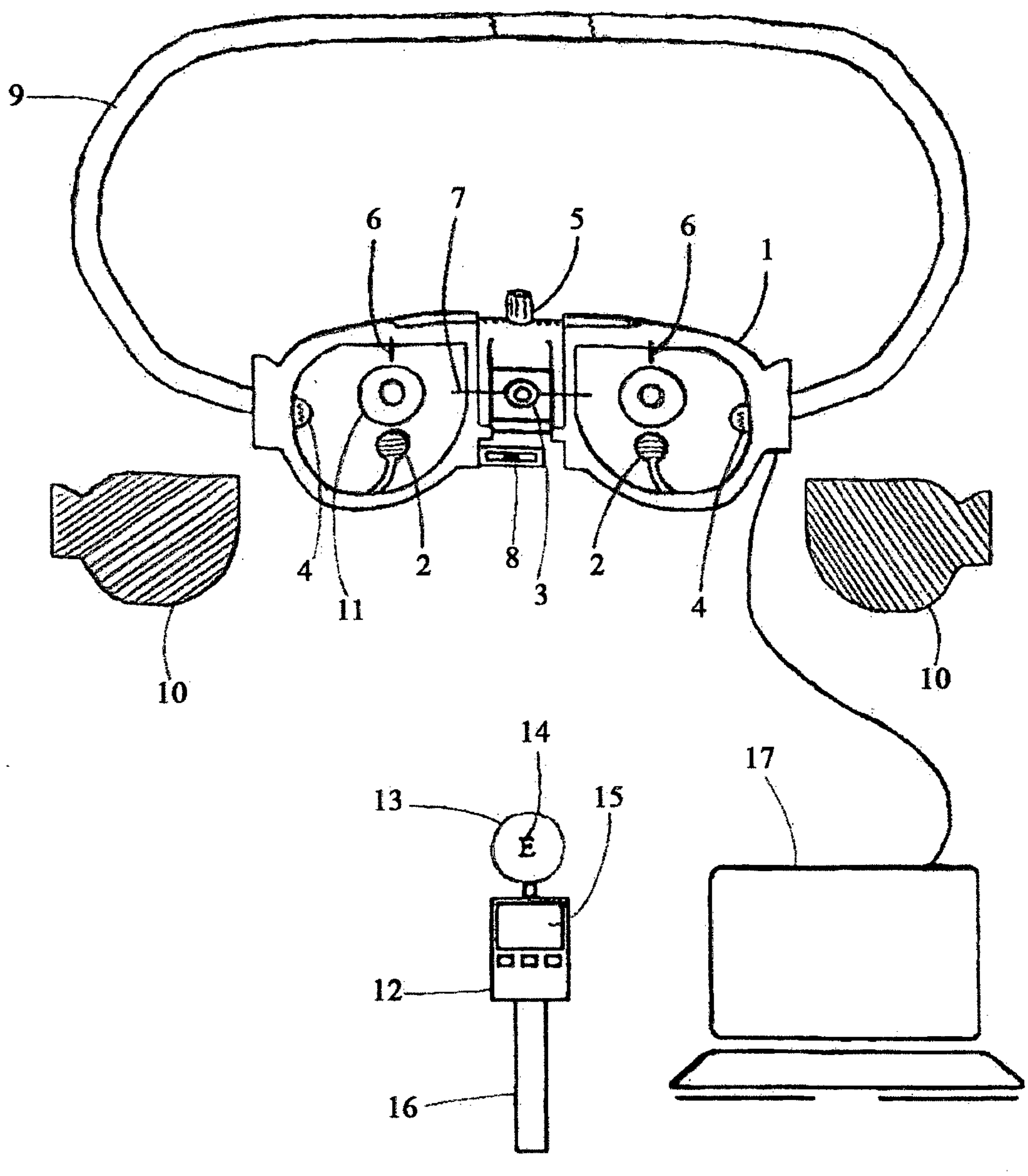

Fig. 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SY 2021/000004

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61B 3/08*** (2006.01); ***A61B 3/113*** (2006.01); ***A61B 3/18*** (2006.01); ***A61B 3/00*** (2006.01); ***G02B 27/00*** (2006.01); ***G06F 3/01*** (2006.01); ***A61B 5/103*** (2006.01); ***A61B 5/11*** (2006.01)
G02B 27/01 (2006.01)

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, G02B, G06F

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)
EPODOC; TXTnn; XP3GPP; XPAIP; XPESP; XPI3E; XPIEE; XPIOP; XPJPEG; XPMISC; XPOAC; XPRD; EMBASE; INSPEC; MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Konrad P. Weber et.al. „Strabismus Measurements with Novel Video Goggles" Ophtalmology, Volume 124, Issue 12, pp. 1849 – 1856, 17.07.2017 [online], [retrieved on 2021-08-26]. Retrieved from the Internet < URL: https://www.sciencedirect.com/science/article/pii/S0161642017311430 > < doi: 10.1016/j.ophtha.2017.06.020 > the entire document, particularly the "Methods" section and Figure 1 along with its respective caption	1-3
X	Oren Yehezkel et.al. „Automated Diagnosis and Measurement of Strabismus in Children" American Journal of Ophthalmology, Volume 213, pp. 226 – 234, 27.12.2019 [online], [retrieved on 2021-08-26]. Retrieved from the Internet < URL: https://www.sciencedirect.com/science/article/pii/S0002939419306191 > < doi: 10.1016/j.ajo.2019.12.018 > The entire document, in particular the "Subjects and Methods" section	1-3
A	US 2016270656 A1 (SAMEC NICOLE ELIZABETH ET AL.) 22 September 2016 (22.09.2016)	1,3

Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2021 (8/27/2021)	31 August 2021 (8/31/2021)

Name and mailing address of the ISA/AT	Authorized officer
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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 2016007124 A1 (EYEBRAIN MEDICAL INC) 14 January 2016 (14.01.2016) the entire document, in particular paragraphs [0018-0020] and [0069-0072] and Figure 6	1-3
A	WO 2008037299 A1 (FLITCROFT DANIEL IAN) 03 April 2008 (03.04.2008) the entire document, particularly page 5, line 25 - page 6, line 25, page 8, lines 6-23 and page 8, line 29 - page 9, line 10	1-3

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