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(54) Title: APPARATUS AND METHOD FOR MONITORING A MEDICAL PROCEDURE

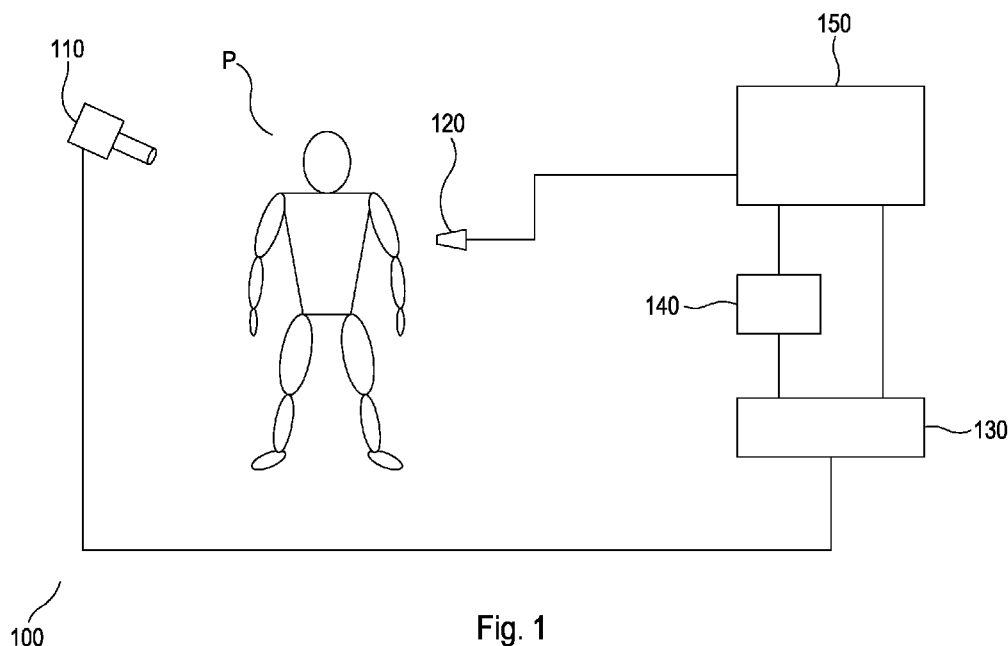


Fig. 1

(57) **Abstract:** An apparatus (100) is used for monitoring a medical procedure, which in this example is to be an axillary PNB. A patient P lies on an operating table (not shown). The patient is to undergo the procedure. A video camera (110) is mounted near the patient and an ultrasound probe (120) is positioned beside the patient in advance of the procedure. Signals from the video camera (110) are fed back to an image processing unit (130) which is located close by the patient. The image processing unit has an artificial intelligence (AI) unit in the form of a deep learning pose estimation module (140), and also directly to a monitor (150). The module (140) also has an output to the monitor, which is positioned within sight of a practitioner (not shown) performing the procedure. The practitioner can observe the monitor during the procedure to receive, for example, confirmation of the correct orientation of the patient for the selected procedure and side, and that the designated procedure is being carried out on the correct side/site of the patient.

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5 APPARATUS AND METHOD FOR MONITORING A MEDICAL PROCEDURE

The present invention relates to an apparatus for monitoring a medical procedure and to an associated method.

10 Carrying out an interventional procedure on a patient on the wrong side of their body, or else at the wrong site, may cause significant, even irreparable, damage to them.

As an example, an ultrasound-guided peripheral nerve block
15 (PNB) can be performed on either the left or right side of the patient, depending on which side anaesthesia/analgesia is required. However, it is very difficult to tell which side of the patient the procedure is being carried out on from the ultrasound image alone: anatomy is mirrored down
20 the midline and therefore looks the same (or similar) on both sides of the patient. Furthermore, the image displayed could reflect laterality from either side of the body depending on the orientation of the ultrasound probe. Because of this, manual checks have been developed to reduce the
25 rate of occurrence of wrong-sided procedures (e.g., WHO surgical safety checklist and the 'Stop Before You Block' campaign from RA-UK). Nevertheless, mistakes still happen: A 10-year surveillance study in the USA identified a wrong-site peripheral nerve block (PNB) rate of 1.28 per 10,000
30 blocks. In the UK, the Safe Anaesthesia Liaison Group identified 67 wrong-side blocks over a 15-month period.

Causes of "wrong-side" mistakes include failures to properly check/confirm/mark the correct side/site, or an incorrect
35 understanding of which side the procedure should be performed

5 on. Another cause, which can occur even when appropriate checks are carried out, is confusion when the practitioner moves from the front to the back of the patient, or when the patient is turned face-up or face-down. Similarly, environmental factors can contribute, such as when equipment
10 set-up or positioning differs from that which the practitioner is used to.

There is therefore a need for improved checking prior to, and during, the procedure to reduce the rate of occurrence
15 of such an error.

Embodiments of the present invention aim to provide an apparatus, and an associated method, for monitoring a medical procedure in which the aforementioned problems are
20 addressed.

The present invention is defined in the attached independent claims, to which reference should now be made. Further, preferred features may be found in the sub-claims appended
25 thereto.

According to one aspect of the present invention, there is provided apparatus for monitoring a medical procedure, the apparatus comprising a camera and an image processing unit,
30 wherein the camera is arranged in use to capture an image of at least a part of a patient and the image processing unit processes image data from the image to determine a configuration of the patient.

5 The apparatus may comprise a monitor, such as a video display monitor, and a result of the processing may be arranged to be displayed on the monitor.

The camera may comprise a video camera and the image may be
10 a video image.

The image processing unit preferably includes an artificial intelligence unit for determining the configuration of the patient.

15 The artificial intelligence unit may comprise a processor and a database. The artificial intelligence unit is preferably arranged in use to apply at least a machine learning process to the image data. In a preferred
20 arrangement, the artificial intelligence unit determines one or more of position, orientation, condition of the patient and/or an anatomical site of the patient.

The video camera may be arranged in use to capture an image
25 of at least a part of a clinician carrying out a procedure on the patient.

In a preferred arrangement, the artificial intelligence unit applies a deep-learning model to the video image data to
30 estimate the pose of both the patient and the clinician carrying out the procedure. Suitable deep learning models for pose estimation area available off-the-shelf, e.g., OpenPose (Z. Cao, G. Hidalgo Martinez, T. Simon, S. Wei, Y. A. Sheikh. *OpenPose: Realtime Multi-Person 2D Pose*
35 *Estimation using Part Affinity Fields*. IEEE Transactions on

5 Pattern Analysis and Machine Intelligence. 2019). Other suitable algorithms to estimate pose may also be used.

In use, the apparatus may be arranged to receive an instruction from an operator regarding the side of the
10 patient that is designated for the procedure. The apparatus is then preferably arranged in use to provide a warning signal as a result of the processing in the event that an incorrect position, orientation, condition of the patient and/or an incorrect anatomical site of the patient is
15 determined by the artificial intelligence unit.

The apparatus may be arranged in use to provide a guidance via the monitor to a clinician when the clinician is positioning an ultrasound probe and/or a surgical tool during
20 the medical procedure.

According to another aspect of the present invention, there is provided a method of monitoring a medical procedure, the method comprising capturing an image of at least a part of
25 a patient and processing the image data to determine a configuration of the patient.

The method preferably comprises displaying a result of the processing on a monitor.
30

The method may further comprise providing guidance via the monitor to a clinician when positioning an ultrasound probe and/or a surgical tool during the medical procedure.

35

5 In a further aspect, the invention provides a computer programme product on a computer readable medium, comprising instructions that, when executed by a computer, cause the computer to perform a method of monitoring a medical procedure, the method comprising capturing an image of at
10 least a part of a patient and processing image data to determine a configuration of the patient.

The invention also comprises a program for causing a device to perform a method of monitoring a medical procedure, the
15 method comprising capturing an image of at least a part of a patient and processing the image data to determine a configuration of the patient.

The invention may include any combination of the features or
20 limitations referred to herein, except such a combination of features as are mutually exclusive, or mutually inconsistent.

A preferred embodiment of the present invention will now be
25 described, by way of example only, with reference to the accompanying diagrammatic drawings, in which:

Figure 1 shows, schematically, an apparatus for monitoring a medical procedure, in accordance with an embodiment of the
30 present invention;

Figure 2 shows, schematically, a display monitor in a first configuration; and

5 Figure 3 shows, schematically, the display monitor of Figure 2 in a second configuration.

Turning to Figure 1, there is shown generally at 100 an apparatus for monitoring a medical procedure, which in this example is to be an axillary PNB. A patient P lies on an operating table (not shown). The patient is to undergo the procedure. A video camera 110 is mounted near the patient and an ultrasound probe 120 is positioned beside the patient in advance of the procedure.

15 Signals from the video camera 110 are fed back to an image processing unit 130 which is located close by the patient. The image processing unit has an artificial intelligence (AI) unit in the form of a deep learning pose estimation module 140, and also directly to a monitor 150. The module 20 140 also has an output to the monitor, which is positioned within sight of a practitioner (not shown) performing the procedure.

25 The practitioner can observe the monitor during the procedure to receive, for example, confirmation of the correct orientation of the patient for the selected procedure and side, and that the designated procedure is being carried out on the correct side/site of the patient, as will now be 30 described.

The static video camera 110 is mounted either in or near the operating field, e.g., on a stand or attached to the ceiling. The video camera 110 captures both the patient P and the practitioner. At the start of the procedure, the practitioner 35

5 indicates to the system the site and side at which the
procedure should take place. This can be incorporated into
recognised safety checklists that are widely employed within
medical practice (e.g., WHO surgical safety checklist and
'Stop Before You Block'). As the procedure is carried out,
10 the video camera 110 captures the scene. The AI module 140
then processes the video stream to determine one or more of:
the location of the patient, the orientation of the patient,
whether the patient is in a prone, supine or lateral state
and the location of the procedure site with respect to the
15 patient (i.e., left vs right and which anatomical region the
current scanning/block pertains to).

The video image data is processed by applying the deep
learning pose estimation model. This extracts the pose of
20 the patient and the clinician performing the procedure and
analyses the relative poses of the two to determine the
patient's location and orientation with respect to the
clinician. The pose estimation data is also analysed to
identify the site and side of the procedure. This is then
25 compared with the known site and side of the procedure as
selected by the clinician.

Based on this data, the AI infers whether the procedure is
being carried out on the same site and side that the
30 practitioner had originally indicated. If not, a warning is
displayed on the monitor. The warning may take the form of
a visual message or indicium, an audible signal or a
combination thereof.

5 For example, Figure 2 shows schematically the monitor 150
and patient P in an example in which the system detects that
the procedure is being carried out on the correct side/site
of the patient. In contrast, Figure 3 shows a situation in
10 side/site of the patient. In this case a warning is issued.

In addition, the system can be used to record a confirmatory
still/video image that demonstrates the side of the patient
on which the procedure was performed, confirm to the
15 practitioner (based on ultrasound probe position) which PNB
was being performed (again, a safety control to check that
the correct block was being done), and, potentially, provide
guidance to the practitioner as to where they need to move
the ultrasound transducer to carry out the PNB (this may use
20 the video data in conjunction with a real-time video feed
from the ultrasound machine).

Although the procedure used as an example above is of a PNB,
the apparatus and methods described herein are applicable to
25 other interventional procedures, including surgery.

In some situations, it may be possible to determine the
side/site of the block from the silhouette of the
patient/practitioner when performing the procedure.
30 However, in other situations it will be difficult to do this
(e.g., ESP block with patient lateral). It may be necessary
to require the practitioner to perform a specific action
prior to starting (e.g. specific hand gesture), to
demonstrate which side they are about to perform the
35 procedure.

- 5 In a further alternative embodiment (not shown) the apparatus may simply indicate what the video camera is looking at, without the requirement of a pre-configured side/site and/or without a warning message.
- 10 Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance, it should be understood that the applicant claims protection in respect of any patentable feature or combination of features referred to herein, and/or
- 15 shown in the drawings, whether or not particular emphasis has been placed thereon.

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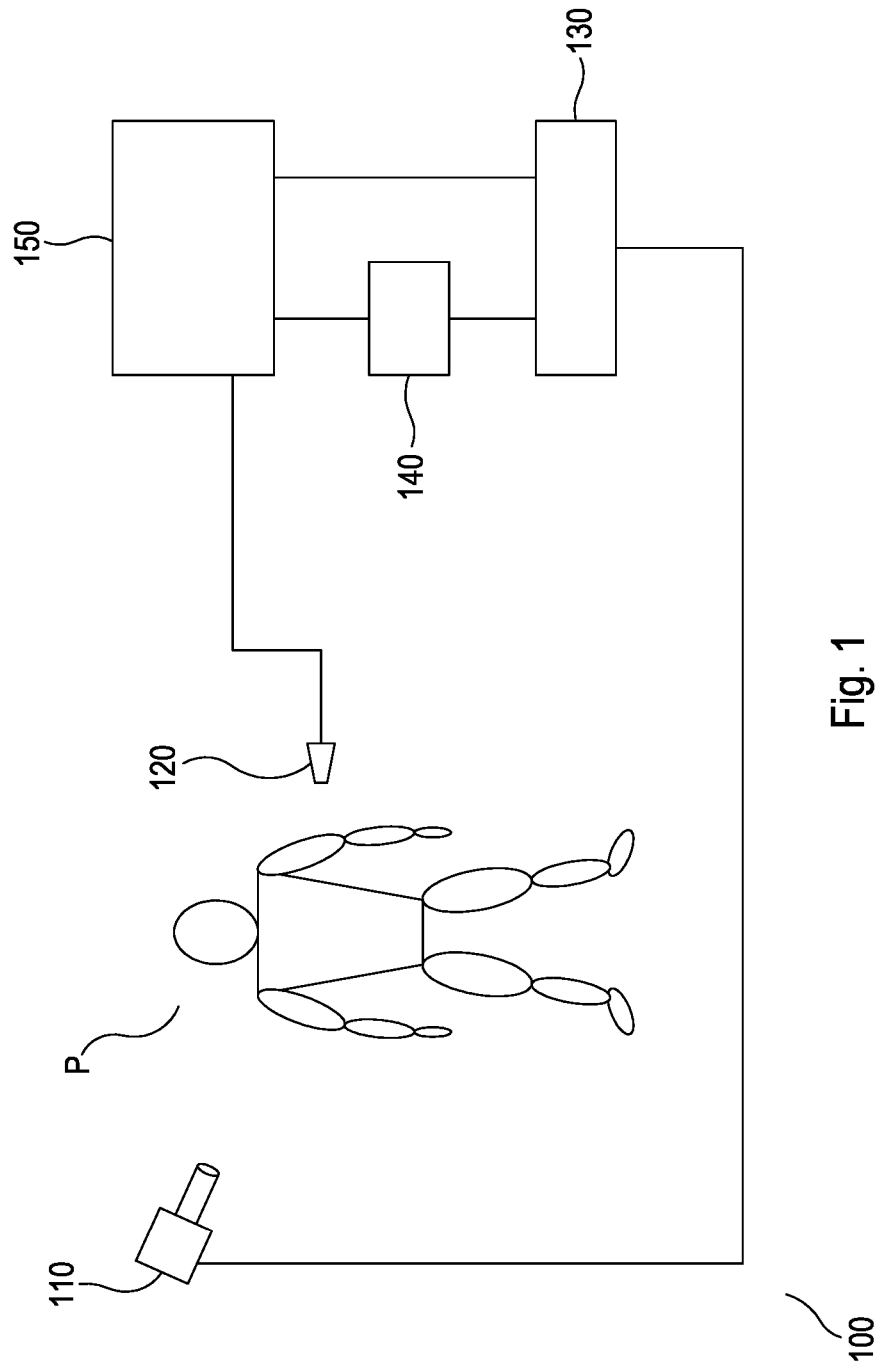
CLAIMS

1. An apparatus for monitoring a medical procedure, the apparatus comprising a camera and an image processing unit, wherein the camera is arranged in use to capture an image of at least a part of a patient and the image processing unit processes image data from the image to determine a configuration of the patient, wherein the image processing unit comprises an artificial intelligence unit arranged in use to determine the position or orientation of the patient and/or an anatomical site of the patient, and wherein the apparatus is arranged in use to provide a warning signal as a result of the processing in the event that an incorrect position or orientation of the patient and/or an incorrect anatomical site of the patient is determined.
2. An apparatus according to Claim 1, wherein the camera is a video camera and the image is a video image.
3. An apparatus according to Claim 3, wherein the image processing unit is arranged in use to apply at least a machine learning process to the image data.
4. An apparatus according to any of the preceding claims, wherein the camera is arranged in use to capture an image of at least part of a clinician.

35

- 5 5. An apparatus according to any of Claims 3-5, wherein the image processing unit applies a deep-learning model to the image data to estimate the pose of the patient, or a clinician, or both.
- 10 6. An apparatus according to any of the preceding claims, wherein the apparatus comprises a monitor, and a result of the processing is arranged to be displayed on the monitor.
- 15 7. An apparatus according to Claim 6, wherein the apparatus is arranged in use to provide a guidance via the monitor to a clinician when the clinician is positioning an ultrasound probe and/or a surgical tool during the medical
- 20 procedure.
8. A method of monitoring a medical procedure, the method comprising capturing an image of at least a part of a patient using a camera, and processing the image data to
- 25 determine a configuration of the patient, wherein the method comprises using an artificial intelligence unit to determine the position or orientation of the patient and/or an anatomical site of the patient, and wherein the method includes providing a warning signal as a result of
- 30 the processing in the event that an incorrect position or orientation of the patient and/or an incorrect anatomical site of the patient is determined.
- 35 9. A method according to Claim 8, wherein the method further comprises providing guidance via a monitor to a clinician

- 5 when positioning an ultrasound probe and/or a surgical
 tool during the medical procedure.
10. A computer programme product on a computer readable
 medium, comprising instructions that, when executed by a
10 computer, cause the computer to perform a method of
 monitoring a medical procedure, the method comprising
 capturing an image of at least a part of a patient and
 processing the image data to determine a configuration of
 the patient.
- 15 11. A program for causing a device to perform a method of
 monitoring a medical procedure, the method comprising
 capturing an image of at least a part of a patient and
 processing the image data to determine a configuration of
20 the patient.



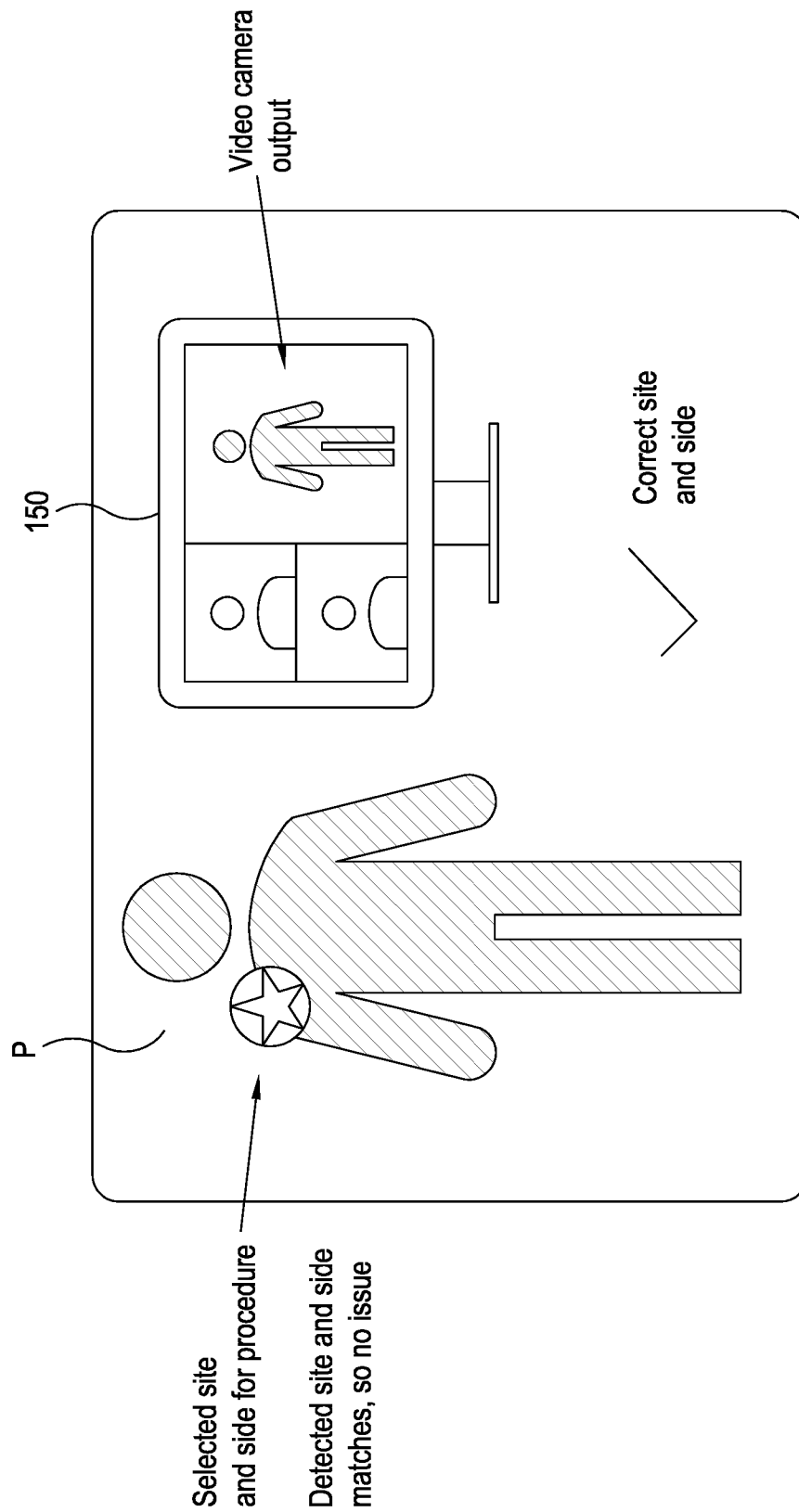


Fig. 2

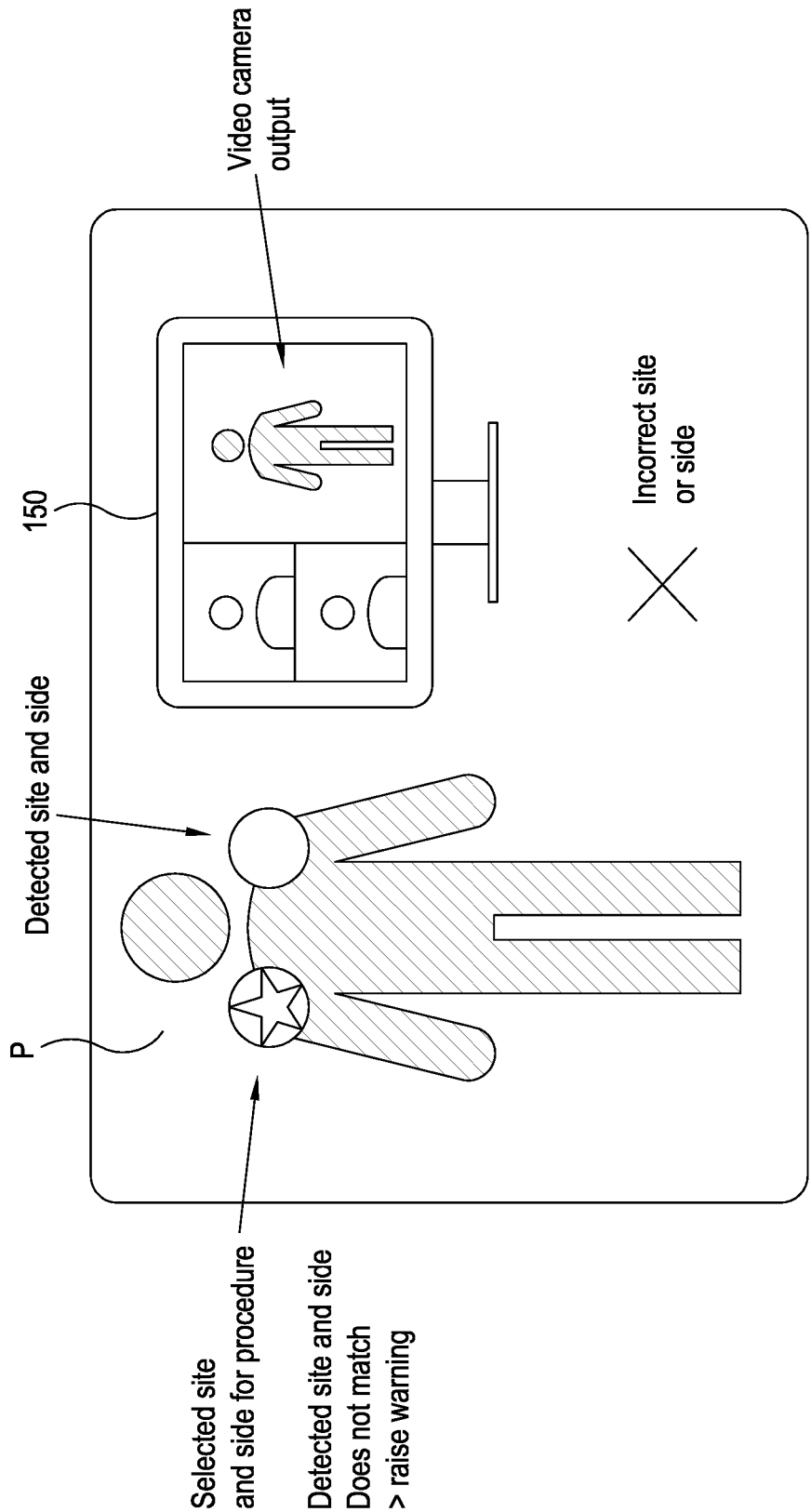


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2023/050502

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	G16H10/60	G16H20/40
		G16H30/40
		G16H70/20
ADD.	G16H40/20	G16H40/63
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) G16H		
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		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 10 610 307 B2 (GEN ELECTRIC [US]) 7 April 2020 (2020-04-07)	1-11
Y	abstract column 1, line 6 - line 7 column 1, line 43 - line 52 column 5, line 29 - line 34 column 5, line 58 - line 61 column 7, line 28 - line 46 column 10, line 54 - line 66 -----	1-11
X	WO 2017/120288 A1 (NEXSYS ELECTRONICS INC [US]) 13 July 2017 (2017-07-13) abstract; figures 12A, 12B paragraph [0002] paragraph [0050] paragraph [0057] paragraph [0067] paragraph [0132] - paragraph [0137] ----- -/-	1-11
☒ 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 an 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 "&" document member of the same patent family		
Date of the actual completion of the international search 19 June 2023		Date of mailing of the international search report 27/06/2023
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Ricciardi, Maurizio

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2023/050502

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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