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(71) Applicant(s):
The University of Sheffield
(Incorporated in the United Kingdom)
Western Bank, SHEFFIELD, S10 2TN,
United Kingdom

(72) Inventor(s):
Ajay Kapoor
Mohamad Jabir
David I Fletcher

(74) Agent and/or Address for Service:
Harrison Goddard Foote
Fountain Precinct, Balm Green,
SHEFFIELD, S1 2JA, United Kingdom

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(56) Documents Cited:
GB 2370877 A
US 5882329 A
US 5308355 A
SU 001629039 A
US 5575789 A
US 5080104 A

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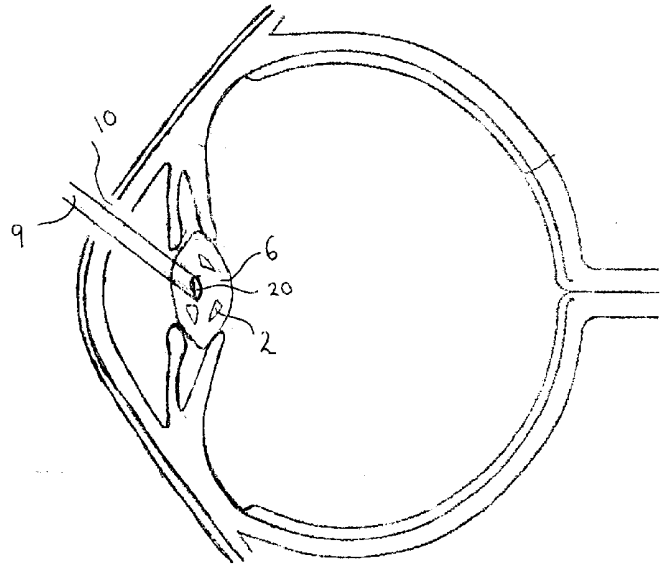
(54) Abstract Title: **Measurement during surgery, especially eye surgery**

(57) A surgical device comprising a surgical instrument 9 and a means for measuring the distance of the implement from a surface 6. The means for measuring the distance from the surface comprises feedback means for providing a surgeon with information on the position of the surgical instrument. The feedback means can provide an audible, visual or tactile signal. The means for measuring can provided with a means for measuring optical change, for example hue and in particular an increase in redness during ultrasonic phaco-emulsification to treat cataracts.

Fig. 1



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

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Fig. 1

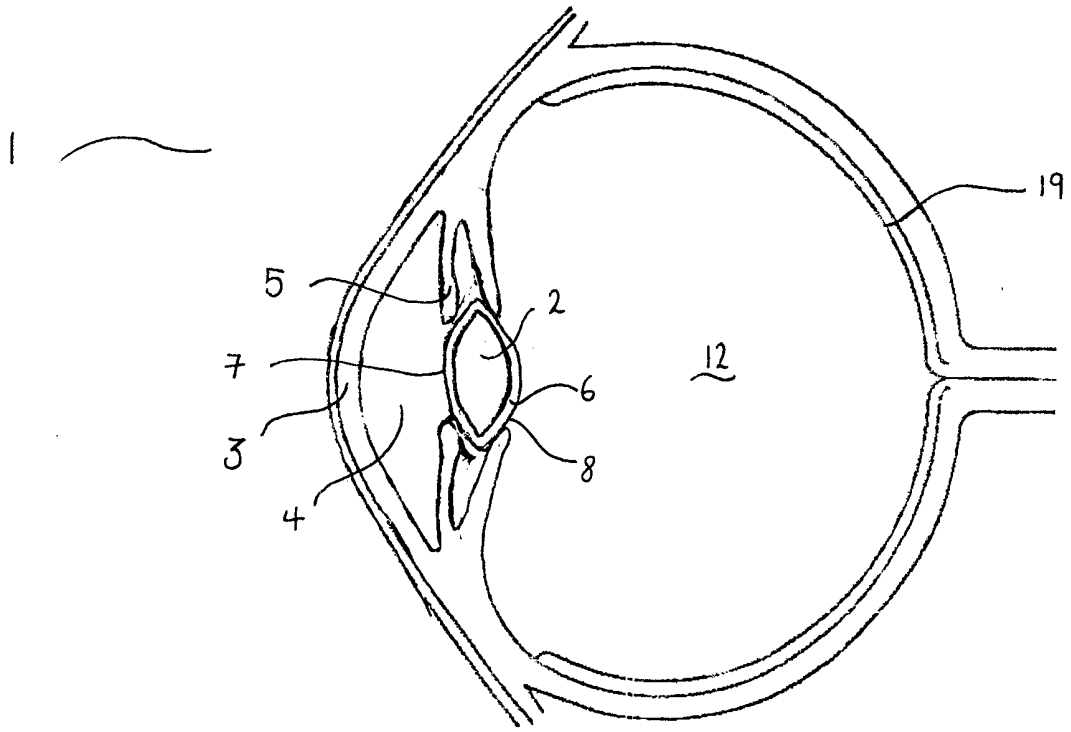


Fig. 1

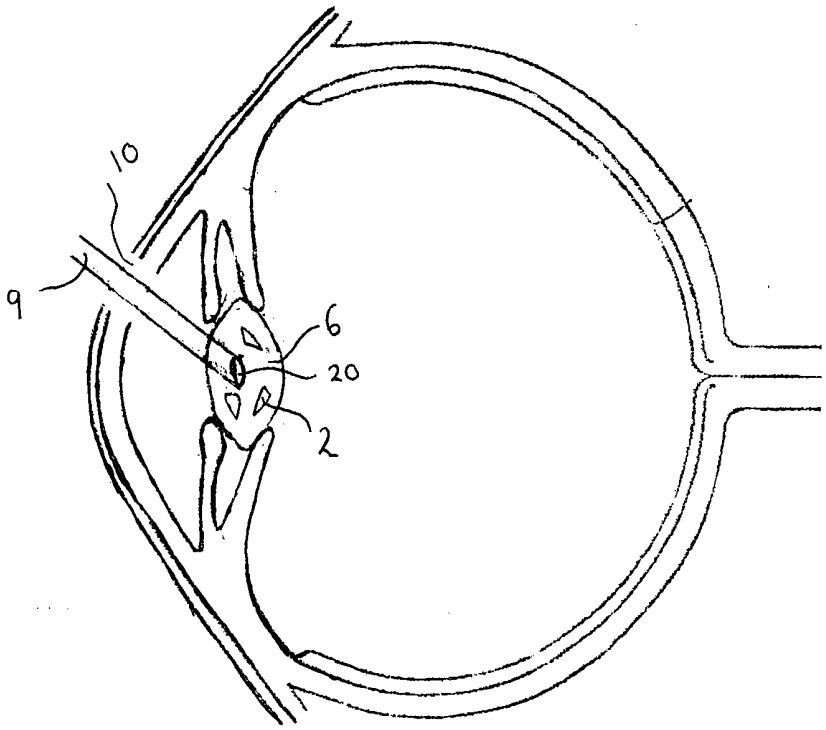


Fig. 3

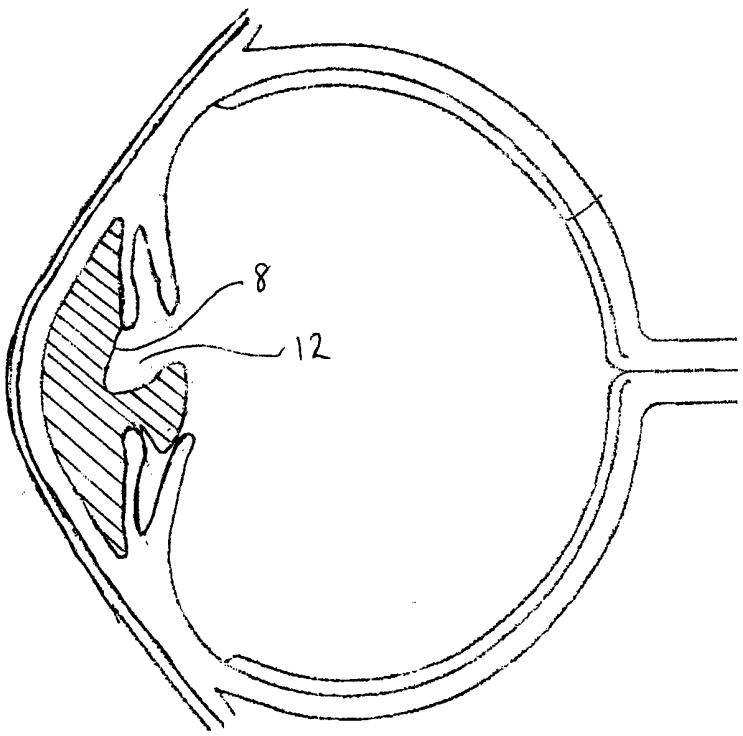
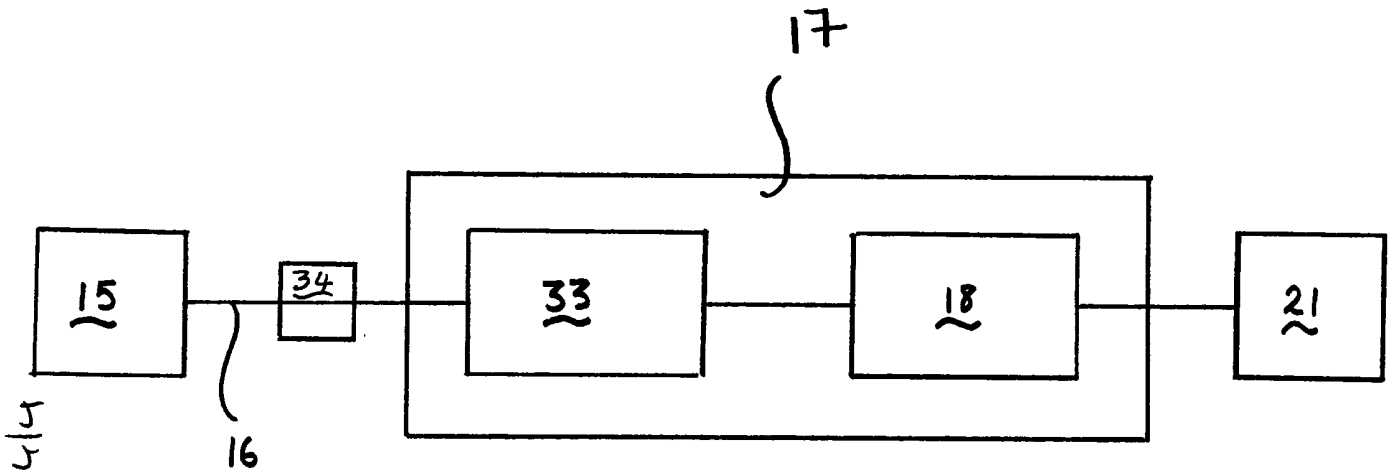


Fig 4



Surgical Device

This invention relates to surgical devices, and more particularly to a surgical device having a position sensing capability.

In modern surgical, especially micro-surgical, techniques, it is frequently necessary for the surgeon to be able to determine the precise location of a surgical implement during a surgical procedure. X-ray techniques, for example, are commonly used for this purpose. However, the skill of the surgeon is still fundamental for many surgical procedures and the estimation of distance of a surgical implement from a vulnerable area is still a matter of judgement.

Cataract is the term used generally to describe the loss of transparency of the eye lens. Cataracts are caused when the protein constituent of the lens becomes uneven and clumps together causing clouds in certain areas of the lens. Early cataracts can be corrected by wearing stronger eyeglasses. However, as the cataract matures, surgery is the only option to correct vision.

One surgical technique employed to remove cataracts is extracapsular extraction. This method requires a 12mm incision to be made in the eye, through which the lens is extracted. An intraocular lens is then inserted into the lens capsule. Once the lens is located in position, multiple sutures seal the eye. The technique can cause rupture of the lens capsule, in particular rupture of the posterior capsule resulting in vitreous loss, as well as astigmatism due to loose or tight stiches.

Phaco-emulsification has been developed in order to

overcome the complications resulting from extracapsular extraction. A 3mm incision is made in the lens capsule and the tip of an ultrasonic vibratable probe (herein called a phaco-tip) is inserted through the incision. Ultrasound energy is then used to fragment and emulsify the lens so that it can be aspirated through the incision.

The most common emulsification technique involves carving a cross in the nucleus of the lens, using the phaco-tip and then dividing the lens into four pieces. The pieces are then free to move making emulsification and aspiration easier. The technique carries the risk of causing posterior capsule rupture and vitreous fluid loss. This is generally as a result of human error, caused by the phaco-tip penetrating and rupturing the posterior capsule. Such errors are particularly significant in inexperienced hands and during training.

The provision of an instrument for fragmenting and removing a cataract with low risk damage to the capsule wall has been reported in US 5,730,718. The invention provides a surface-discriminating fragmenting tool that fragments and permits aspiration of high mass rough surface, rigid tissue, without damaging nearby smooth, flexible low mass walls. The tool does not eliminate the danger of penetrating the posterior capsule as a result of surgeon error.

US 5,540,690 discloses a phaco-shield for placement over an eye prior to surgery to prevent contact between the leading edge of the phaco-probe and the posterior capsule of the eye. The shield partially surrounds the nucleus of the lens to be shattered. The phaco-probe is disposed within the shield, and designed so that it never extends

beyond the outer extremities of the shield. The shield severely limits the freedom of the surgeon to operate within the lens capsule, the inability to move the phaco-probe within the eye potentially impacting upon the success of the surgery.

It will be apparent that in cataract removal and many other surgical techniques the surgeon is in need of better information about the location of the surgical implement.

In a first aspect, the present invention provides a surgical device comprising a surgical implement and means for measuring the distance of the implement from a surface.

The invention is particularly applicable to phaco-emulsification devices and will henceforth be more particularly described with reference thereto. It is to be understood, however, that the invention may equally be applied to other ultrasonic probes, laser devices, cutting knives and other surgical implements in appropriate circumstances. Preferably, the surgical implement comprises an ultrasonic vibratable probe having a phaco-tip.

Preferably the means for measuring the distance of the implement from the surface comprises feedback means for providing the surgeon with real-time, preferably continuous, information on the position of the surgical instrument. Such information can be visual or tactile, but is preferably aural, so that the attention of the surgeon is not distracted by having to look at, for example, a screen. Alternatively, if the surgical technique involves the use of a microscope the

information could be displayed in the view piece or view finder of the microscope.

In one embodiment the feedback means provides the surgeon with information on the position of the surgical instrument only when the distance between the implement and the surface reaches a specified figure.

The means for measuring the distance of the implement from the surface can comprise any suitable means for measuring a physical change. Such a change can be, for example, a change in electrical impedance, or a change in acoustic impedance. Alternatively, a triangulation method may be employed, in which the relative position of a source, which can be an image of the implement, or a magnetic source, is measured.

Preferably the means for measuring the distance of the implement from the surface comprises means for detecting an optical change. Preferably the optical change is a change in hue.

According to a preferred aspect of the present invention there is provided a surgical device for eye surgery, the eye comprising a cornea, an iris and a lens, the lens comprising an anterior capsule, a posterior capsule and lens matter, and especially for cataract removal, which comprises :

a) a surgical implement;
b) means for detecting changes in hue visible through the eye lens during surgery; and
c) feedback means

wherein the feedback means receives an output from the detecting means and provides a signal to a surgeon

controlling the surgical instrument indicating the distance of the implement from the posterior capsule.

In a further aspect, the invention also provides a method of reducing rupturing of the posterior capsule during eye surgery comprising:

a) measuring changes in hue visible through an eye lens during surgery; and

b) providing feedback to a surgeon controlling a surgical implement about the changes in hue;

wherein a change in hue indicates a change in distance between the surgical implement and the posterior capsule.

By hue, in this specification, is meant a measure of the relative amounts of the additive primary colours which contribute to the colour of an object. By additive primary colours is meant the spectral colours red, green and blue.

In a preferred embodiment of the invention, an increase in redness of hue indicates a reduction in distance between the surgical implement and the posterior capsule.

In a further preferred embodiment of the invention, means for recording the hue are provided. The recording means may operate intermittently, but is preferably continuous. Any suitable means for recording visible hue can be used, for example, a video recorder, or similar device.

Preferably the device comprises means for capturing the hue visible through an eye lens during surgery, said

means comprising a camera, especially a digital camera, providing a signal output of captured images to a processor.

In a further preferred embodiment of the invention, said processor comprises a PC or similar processing means. The PC or similar processing means preferably processes information concerning changes in hue, for example an image signal from a digital camera, continuously in order to obtain a real time reading. Alternatively, the PC or similar processing means may take signal readings at specified intervals. For example, the PC or similar processing means may read the RGB values (as hereinafter defined) of the image signal, the intensity value of the image signal or the HSV Colour Space values (as hereinafter defined) of the image signal.

In a further preferred embodiment of the invention, the feedback means emits an audible signal. Preferably said audible signal is in the form of a beep and said signal is fed into an earpiece worn by the surgeon. The beep can be intermittent or continuous.

In a preferred embodiment of the invention, an increase in redness of hue results in an increase in frequency or pitch of the audible signal.

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows a cross sectional view of an eye;

Figure 2 shows a cross sectional schematic representation of a phaco-emulsification probe in the

lens capsule of the eye;

Figure 3 shows a cross sectional view of the eye of figure 1, the eye having a ruptured posterior capsule and vitreous loss; and

Figure 4 shows a schematic representation of a device according to an embodiment of the invention.

Referring to figure 1, an eye is illustrated generally at 1. A lens 2 is positioned behind a cornea 3, an anterior chamber 4 and an iris 5. The lens 2 comprises a lens capsule 6 comprising a front anterior capsule 7 and a rear posterior capsule 8. Vitreous fluid 12 fills the chamber adjacent to the posterior capsule 8. A retina 19 is located so that the lens can focus light thereon.

During cataract surgery using phaco-emulsification, a phaco-probe 9 having a phaco-tip 20, is inserted into the lens capsule through a small incision 10, as illustrated in figure 2. The phaco-tip 20 emits an ultrasonic sound wave into the lens matter that fragments and emulsifies the lens. The emulsified lens 2 is then aspirated through a suction channel 11 in the phaco-tip 20.

Figure 3 illustrates a common complication that results from removal of the lens 2 using a phaco-tip 20. The phaco tip 20 ruptures the posterior capsule 8 resulting in loss of vitreous fluid 12.

An embodiment of a device according to the invention is illustrated schematically in figure 4. The device comprises camera 15 for receiving images from lens 2 of the eye 1 during eye surgery. The camera 15 detects the hue visible through the lens 2 during the course of the

surgery.

The camera 15 produces captured images that are input to a processor 17, comprising a processing means 33 and a signal generating means 18. The images are input into the processing means 33 through a cable 16. Optionally the images from the camera can be sent to a recorder 34 before entering the processor 17. The processing means 33 measures changes in hue visible through the lens during the course of the surgery and produces an output that varies according to change measured.

The output from the processing means 33 is fed to the signal generating means 18. The signal generating means in turn generates an output to an ear-piece 21, via a cable or wireless emission means, which provides an audible signal which alerts the surgeon to changes in the output of the processor 17 and thereby to changes in hue visible through the lens. Through simple training procedures the surgeon can readily learn to recognise changes in frequency and/or pitch of the audible signal and relate these to the distance of the phaco-tip from the posterior capsule.

In one embodiment, the output from the camera is fed directly to a processing device, for example a PC, which processes the output and provides a real time signal directly to the feedback means.

In another embodiment of the invention, the system also comprises recording means, for example, a video recorder. The video recorder, records real time images of the lens of the eye during surgery. The recorded images are used as input for a PC provided with a video card and the appropriate software to measure changes in hue visible

through the lens, which serves as the processing means.

The device can measure changes in hue visible through the lens in a variety of possible ways. Firstly the images can be read as RGB (Red-Green-Blue) images. The intensity of each colour relative to one another can be used to measure changes in hue. Alternatively, the intensity of one colour can be used to measure changes in intensity of that colour alone, for example changes in intensity of red hue.

Alternatively, the PC can read the images as GREY images. The intensity values of the additive primary colours are combined to give one value for average intensity, rather than three separate values for each colour.

As a further alternative, the PC can read the images using HSV colour space analysis (Hue, Saturation, Value). Using this analysis the scale of hue varies from 0 to 1.0, with corresponding colours varying from red, through to yellow, green, cyan, blue, magenta and back to red. Saturation is measured on a scale of 0 to 1.0, the corresponding hues varying from shades of grey (unsaturated) to those having no white component (fully saturated). Finally, value measures the brightness varying from 0 to 1.0, hues being brightest at 1.0.

By way of example only, the device can be used in a method to reduce rupture of the posterior capsule during cataract surgery, by alerting the surgeon to the proximity of the phaco-tip to the posterior capsule in the following manner.

As the surgery progresses the hue visible through the lens changes due to emulsification and aspiration of the

lens. In particular, the intensity of red in the hue increases relative to blue and green. This is due to the retina becoming increasingly visible as the lens is emulsified. A video recorder records real time images of the lens during the surgery and inputs the images to a PC for processing. The PC, using RGB analysis, measures changes in intensity of hue, in particular changes in intensity of red hue. The changes in intensity are used to provide an audible signal, in the form of a beep, which increases in frequency as the intensity of the red hue increases. As such the surgeon receives an audible signal that alerts him to the amount of lens removed and thus the proximity of the phaco-tip to the posterior capsule.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series

of equivalent or similar features.

The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Claims:

1. A surgical device comprising a surgical implement and means for measuring the distance of the implement from a surface.

2. A surgical device according to claim 1, wherein the surgical implement comprises a phaco-emulsification device.

3. A surgical device according to claim 1 or 2, wherein the surgical implement comprises an ultrasonic probe.

4. A surgical device according to any of the preceding claims, wherein the means for measuring the distance of the implement from the surface comprises feedback means for providing the surgeon with information on the position of the surgical implement.

5. A surgical device according to claim 4, wherein the feedback means provides an audible signal.

6. A surgical device according to any of the preceding claims, wherein the means for measuring the distance of the implement from the surface comprises means for detecting an optical change.

7. A surgical device according to claim 6, wherein the optical change detected is a change in hue.

8. A surgical device according to any of the preceding claims, for eye surgery, the eye comprising a lens, a cornea, an iris, an anterior capsule and a posterior capsule, which comprises :

a) a surgical implement;

b) means for detecting changes in hue visible through the eye lens during surgery; and

c) feedback means

wherein the feedback means receives an output from the detecting means and provides a signal to a surgeon controlling the surgical implement indicating the distance of the implement from the posterior capsule.

9. A surgical device for reducing the risk of rupturing of the posterior capsule during eye surgery comprising:

a) means for capturing the hue visible through an eye lens during surgery;

b) means for measuring changes in hue visible through the eye lens during surgery; and

c) feedback means

wherein a captured image of the hue is used as an input for the means for measuring changes in hue and a change in hue is used as an input to the feedback means which provides a signal to alert a surgeon controlling the surgical device to said change 10.

10. A surgical device according to claim 7, wherein an increase in redness of hue indicates a reduction in distance between the surgical implement and the posterior capsule.

11. A surgical device according to claim 8 or 9, wherein said eye surgery is cataract surgery.

12. A surgical device as claimed in claim 11, wherein said cataract surgery comprises phaco-emulsification.

13. A surgical device according to claim 9, wherein the feedback means provide a real time signal to the surgeon.

14. A surgical device as claimed in claim 6, which also comprises means for recording the optical change.

15. A surgical device as claimed in claim 14, wherein the means for recording is a video recorder.

16. A device as claimed in any preceding claim, wherein said means for measuring comprises a PC.

17. A device as claimed in claim 16, wherein said PC reads the RGB values of the recording at specified intervals, or wherein said PC reads the intensity value of the recording at specified intervals, or wherein said PC reads the HSV Colour Space values of the recording at specified intervals.

18. A device as claimed in claim 5, wherein said audible signal is fed into an earpiece adapted to be worn by a surgeon.

19. A device as claimed in claim 18, wherein an increase in redness of hue results in an increase in frequency of audible signal.

20. A method of reducing the risk of rupturing of the posterior capsule during eye surgery comprising:

d) measuring changes in hue visible through an eye lens during surgery; and

e) providing feedback to a surgeon controlling a surgical implement about the changes in hue

wherein a change in hue indicates a change in distance between the surgical implement and the posterior capsule.

21. A method according to claim 20, wherein an increase in redness of hue indicates a decrease in the distance between the surgical implement and the posterior capsule.

22. A method as claimed in claim 20 or 21, wherein said eye surgery is cataract surgery.

23. A method as claimed in claim 22, wherein said cataract surgery comprises phaco-emulsification.

24. A method as claimed in any of claims 20 to 23, wherein said measuring of changes in hue comprises recording images of the eye lens during surgery and processing the recording to provide an output informative about changes in hue.

25. A method as claimed in any one of claims 20 to 24, wherein said measuring of changes in hue comprises reading the RGB values of the recording continuously or at specified intervals, or reading the intensity value of the recording continuously or at specified intervals, or reading the HSV Colour Space values of the recording continuously or at specified intervals.

26. A method according to claim 24 or 25, wherein said output is input to a feedback device adapted to provide feedback to the surgeon about changes in hue.

27. A method according to claim 26, wherein said feedback device emits an audible signal and comprises

an earpiece adapted to be worn by the surgeon.

28. A position measuring device for a surgical instrument for measuring the distance of the implement from a surface.

29. A position measuring device according to claim 28,wherein said device comprises a feedback means for providing a surgeon with information on the position of the surgical implement.

30. A position measuring device according to claim 29, wherein the feedback means provides an audible signal.

31. A position measuring device according to any of claims 28 to 30, wherein the means for measuring the distance of the implement from the surface comprises means for detecting an optical change.

32. A position measuring device according to claim 31, wherein the optical change detected is a change in hue.

33. A surgical device substantially as hereinbefore described with reference to and as illustrated in the accompanying Drawings.

34. A surgical device substantially as hereinbefore described.

35. A method of reducing the risk of rupturing of the posterior capsule during eye surgery substantially as hereinbefore described.

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Application No:	GB 0315449.9	**Examiner:**	Karl Whitfield
Claims searched:	1 to 8, 10, 14, 15, 18 to 32 and 11, 12, 16, 17, 33, 34 and 35 in part	**Date of search:**	18 November 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1, 4, 28 & 29 at least	GB 2370877 A	(CARL ZEISS) claims 22 to 27
X	1, 28 & 29 at least	US 5882329	(PATTERSON et al.) whole document
X	1, 4, 28 & 29 at least	US 5308355	(DYBBS) abstract
X	1, 28 & 29 at least	US 5575789	(BELL et al.) see abstract
X	1, 28 & 29 at least	US 5080104	(MARKS et al.) whole document
X	1, 4, 28 & 29 at least	SU 1629039	(KAGAN) abstract

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X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
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&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

A5R

Worldwide search of patent documents classified in the following areas of the IPC[7]:

A61B, A61F

The following online and other databases have been used in the preparation of this search report:

Online databases: Derwent World Patents Index, Patent Abstracts of Japan and European Patent Office