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(54) GUIDED ENDOTRACHEAL INTUBATION SYSTEM

SYSTEM ZUR GEFÜHRTEN ENDOTRACHEALEN INTUBATION

SYSTÈME D'INTUBATION ENDOTRACHÉALE GUIDÉE

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to the field of endotracheal intubation, especially using external illumination to assist in the positioning of the endotracheal tube in the trachea of the subject.

BACKGROUND OF THE INVENTION

[0002] Endotracheal intubation is a well-known and widely used practice performed when normal ventilation of the patient's lungs may be impaired. Failure to artificially ventilate an apneic patient rapidly could result in serious brain damage or death. During patient intubation, a flexible tube, also known as an endotracheal tube, is used. A distal end of the tube is placed within the patient's trachea. The proximal end of the tube can be attached to a resuscitator bag or any other device, supporting the respiratory process. During patient intubation, there is a risk of accidental misplacement of the endotracheal tube into the esophagus. This condition can in itself cause death and disability if not quickly detected. When performing tracheal intubation, a common method is to use an imaging device usually in the form of a fiber-optic endoscope or using a device that consists of a rigid body with a camera in its distal end. Both classes of devices provide an image of the patient's vocal folds and the glottis, in order to facilitate tracheal intubation. However, when using internally illuminated endoscopic images, it is often difficult for the user to identify the exact trachea location in order to ensure performing the intubation properly, especially in trauma cases, where blood and secretions may be present, and where speed may be vital. A number of prior art publications suggest the use of illumination applied externally to the neck of the patient, in the region of the vocal cords, so that the preferentially illuminated trachea becomes prominently visible, and thus easier to target by the user, or by an automatic homing device for the endotracheal tube.

[0003] In US Patent No. 6,161,537 to D. Gravenstein et al, for "Transtracheal Energy Application and Sensing System for Intubation: Method and Apparatus", there is described such a system. In order to accommodate differences in transmission of the external illumination into the glottal region of the patient's throat, the external light source is controlled by means of electronic feedback circuitry connected to and driven by the detected signal processing system, for providing an auto-gain feature. This thus involves the use of a controllable level illumination source for the tracheal identification, concomitant control circuitry and a feedback link from the user signal processing and viewing module to the externally applied tracheal identification illumination.

[0004] In US Patent Application Publication No. US 2011/0178369, for "System and Method for Intubation" to C. Cui, there is described an automatic endotracheal tube intubation system and method, using an external trachea identifier source, which can be a light source, disposed on the patient. However, nowhere in this reference is there mentioned any provision for controlling the intensity level of the external trachea identifier source, which is likely to be necessary to enable efficient and positive video identification of the correct insertion into the trachea.

[0005] There therefore exists a need for an endotracheal tube placement and monitoring system, which is convenient to use and of low cost, and which overcomes at least some of the disadvantages of prior art systems and methods.

SUMMARY

[0006] The present disclosure describes new exemplary systems for the simple yet accurate viewing, guidance and execution of endotracheal intubation. The invention is defined by claim 1. The system utilizes a self-powered, stand-alone external illumination source, supplying a fixed output level of modulated illumination, applied externally to the region of the neck of the subject immediately external to the larynx region. The illumination source can be constructed in the form of a patch applied externally to the patient's throat region, and, because of its simple low-cost manufacture, could be a disposable component for single-event use with the instrument. This illumination is detected by an imaging system which receives its input from an endotracheal placement device, which can either have a detector array at its distal end, or can transmit the imaged view fiber-optically to a detector array disposed in the electronic sensing and control unit. The externally generated illumination is modulated, most conveniently by amplitude modulation, to enable the perceived or apparent imaged level to be adjusted by signal processing of the illumination detected internally within the subject's throat, and to enable effective discrimination and control of the external illumination penetrating into the trachea, as perceived by the sensing and control system, from the internal illumination provided by the endotracheal tube. The discrimination and level control can be achieved by using phase manipulation of the modulated illumination sensed, without the need for any inputs to the external illumination source at all, which itself provides a constant predetermined modulated output level of illumination.

[0007] This system enables the user to adjust the level of apparent tracheal illumination seen in the endoscopic images generated, the term apparent being used to emphasize that the actual tracheal illumination emitted from the trachea is constant (provided that the external illumination source is not moved, and that the patient does not move) and the different illumination level perceived is achieved by signal processing performed on the received image data. This system also enables the control system to use this perceived image data of the trachea to effectively perform automatic illumination level control, and

automatic or semi-automatic steering of the endotracheal tube towards the trachea entrance, using images or image data having predetermined illumination and contrast characteristics.

[0008] The system enables the maintenance of the apparent imaged intensity of the light received from the external source at a level optimized for the detection of the trachea. If the level is too weak, the trachea may not be positively detectable, and if it is too strong, illumination may be collected from both the trachea and the esophagus, or light may be reflected or scattering from the surrounding tissues, thereby causing anatomical identification errors. Furthermore, as the location of the distal end of the endotracheal tube changes as it is advanced down the throat towards the vocal cords, or even into the trachea, the distance to the light source changes significantly, and the level of detected external illumination also changes.

[0009] Control of these changes is achieved in the present described systems without the need for any feedback mechanism that adjusts the intensity of the light source itself, which can be an autonomous element, unconnected electronically or wirelessly to the sensing and display control system. The image intensity control is performed entirely by signal processing within the sensing and display unit, increasing or decreasing the modulated light component of the image so that its apparent intensity remains optimal, before displaying it to the user, or before using it for a task such as intubation tube guidance.

[0010] The modulated illumination emitted by the external source should advantageously be at a wavelength which is readily transmitted through the tissues of the throat, such that it penetrates without undue attenuation, and also which has good detection sensitivity by commonly used photo-sensors, such as silicon-based CCD or CMOS arrays. Therefore, it is to be understood that use of the terms "light" or "illumination" in this disclosure is not intended to be limited to the visible region, but is understood to include any wavelength region which can thuswise be used by the system. Additionally, the modulation frequency should be commensurate with the frame frequency of readily available and standard video imaging devices, thereby keeping the system simple and of low cost.

[0011] Furthermore, although the system has been generally described in this disclosure, in terms of a video image display system, this being a commonly used output for visually facilitating endotracheal intubation, it is to be understood that the apparatus and methods of this disclosure can equally well be used in order to provide image data output for use in generating automatic gain control for the images or parts of the images to be generated, or in order to provide data for automatic guidance of the intubation tube during insertion.

[0012] Additionally, for an immobile patient and firmly affixed external light source, the modulated illumination level which penetrates the trachea and is then detected as being emitted from the trachea, has an effectively constant level. Therefore, it is to be understood that references made to the sensed or perceived or apparent illumination level, or similar language, are intended to refer to the output of the control and display system after signal processing of the image data, to enhance or amend the content of the true illumination detected. This is applicable whether the image is in a true displayed image form, or as image data for use in control tasks. Such terms are also to be thuswise understood when claimed.

[0013] There is thus provided in accordance with an exemplary implementation of the devices described in this disclosure, a system for performing guided tracheal intubation on a subject, comprising,

(i) an autonomous light source, providing a substantially constant level modulated illumination output, adapted to be externally applied to the neck of the subject in the region of the subject's larynx,

(ii) an optical sensing system receiving a stream of image data from an endotracheal placement device within the throat of the subject, the optical image data including data relating to the level of the modulated illumination which has penetrated the trachea of the subject, and

(iii) a control system adapted to perform signal processing on modulated content of the received stream of image data, and to generate image output data which enables the apparent sensed level of illumination from the trachea to be adjusted.

[0014] In such a system, the autonomous light source is unconnected to the control system by wire or wirelessly. Additionally, the signal processing may utilize phase manipulation of the optical image data, in order to discriminate between the modulated illumination which has penetrated the trachea of the subject, and illumination applied internally to the subject's larynx region from the endotracheal placement device. Furthermore, the apparent sensed level of illumination from the trachea may be adjusted by a user of the system during the guided tracheal intubation. Alternatively or additionally, the apparent sensed level of illumination from the trachea may be adjusted automatically to provide a predetermined level of contrast in images generated from the image data.

[0015] In further exemplary implementations of the above mentioned systems, the autonomous modulated light source may comprise at least one battery, at least one light emitter, and a circuit for powering the at least one light emitter. In this implementation, the at least one light emitter may be a light emitting diode. In any of the previously mentioned systems, the illumination may have a wavelength within the range of from 0.4 micrometers to 1.4 micrometers.

[0016] In yet other implementations, the autonomous modulated light source may comprise either an adhesive element or a strap, for application to the neck of the subject in the region of the subject's larynx. The autonomous modulated light source may also be adapted to be dis-

posable after a single use.

[0017] Another example implementation involves a patch adapted to be externally applied to the neck of a subject, comprising:

(i) at least one battery,
(ii) at least one light emitter, and
(iii) an electronic circuit for powering the at least one light emitter such that it emits modulated illumination,

wherein the patch is adapted to penetrate the modulated illumination into the trachea of the subject such that an optical sensing system associated with an endotracheal placement device within the throat of the subject, can detect that part of the modulated illumination penetrating the trachea.

[0018] In such an implementation, the patch need have no functional connection with the optical sensing system by wire or wirelessly. Additionally, the modulated illumination may be emitted at a substantially constant power level. The patch may most conveniently be disposable. The methods described herein are not part of the invention. There is further provided yet other implementations describing a method of performing guided tracheal intubation on a subject, comprising,

(i) externally illuminating the neck of the subject in the region of the subject's larynx with an autonomous light source providing a substantially constant level, modulated illumination output,
(ii) inserting an endotracheal placement device into the throat of the subject,
(ii) optically sensing a stream of optical image data received from an endotracheal placement device inserting into the throat of the subject, the optical image data including data relating to the level of the modulated illumination which has penetrated the trachea of the subject, and
(iii) performing signal processing on modulated content of the received stream of image data to generate image output data which enables the apparent sensed or perceived level of illumination from the trachea to be adjusted.

[0019] In such a method, the sensed level of illumination from the trachea may be adjusted without any connection to the autonomous light source by wire or wirelessly. Additionally, the signal processing may utilize phase manipulation of the optical image data, in order to discriminate between the modulated illumination which has penetrated the trachea of the subject, and illumination applied internally to the subject's larynx region from the endotracheal placement device. Furthermore, the apparent sensed or perceived level of illumination from the trachea may be adjusted by a user of the system during the guided tracheal intubation. Alternatively or additionally, the apparent sensed level of illumination from the trachea may be adjusted automatically to provide a predetermined level of contrast in images generated from the image data.

[0020] According to further exemplary methods, any of the above mentioned methods may be performed with the autonomous modulated light source comprising at least one battery, at least one light emitter, and a circuit for powering the at least one light emitter. In that case, the at least one light emitter may be a light emitting diode. In any of these methods, the illumination may have a wavelength within the range of from 0.4 micrometers to 1.4 micrometers.

[0021] In yet further implementations, the autonomous modulated light source may be applied to the neck of the subject by use of an adhesive element or a strap. Additionally, the autonomous modulated light source may be disposed after a single use.

[0022] In any of the above described systems and methods, the sampled image data may need to be obtained at a frequency at least twice as high as the frequency of the modulated illumination output. Furthermore, the modulated illumination output may be square wave or sinusoidally modulated. Finally, in any of the above described embodiments, the stream of image data may conveniently be a video stream of images.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 shows schematically a conventional endotracheal procedure being performed on a patient;
Fig. 2 is a schematic view of a prior art sensing system for tracheal intubation, making use of an externally applied illumination source;
Fig. 3 schematically shows the system architecture of the prior art intubation system shown in Fig. 2;
Fig. 4A illustrates schematically a novel intubation illumination system of the present disclosure, while Fig. 4B is a schematic drawing of an exemplary disposable illumination patch for use in the system of Fig. 4A;
Figs. 5 schematically shows the system architecture of the intubation system of Fig. 4A;
Figs. 6A-6G illustrate the use of phase sensitive detection techniques on received modulation pulse trains for a method of viewing endoscopic intubation and for controlling the displayed image intensity, using the system of Fig. 4; and
Figs. 7A-7E illustrate an alternative method to that of Figs. 6A-6G, in such a manner that the external intensity can be rendered to be the major or even the only component shown in the display system.

DETAILED DESCRIPTION

[0024] Reference is now made to Fig. 1, which illus-

trates schematically a conventional endotracheal procedure being performed on a patient 10. The trachea 11 is shown in its location in front of the esophagus 12, and an endotracheal intubation tube 13 has been successfully inserted past the epiglottis 14 and past the vocal chords 15 which are located at the junction of the trachea 11 and the esophagus 12, into the trachea. The problem of successfully negotiating the junction of the trachea and the esophagus is clear from Fig. 1. In commonly used procedures, the attending personnel manipulate the intubation tube into its correct position in the trachea by endoscopically viewing the progress of the distal tip of the intubation tube using illumination conveyed internally down the intubation tube assembly.

[0025] Reference is now made to Fig. 2, which is a schematic view of a prior art sensing system for tracheal intubation, as described in the above mentioned US Patent No. 5,560,351 to Gravenstein et al. In this system, an energy source 21, which is conveniently an optical source, conveys illumination down a light guide 22 to the external region 23 of the patient's throat, and the light passing through the tissue of the patient's throat illuminates the trachea far more strongly than the esophagus. An endoscopic intubation tube 24 provides an image of the junction region, which is viewed in the display and processing, and steering system 25. Because of the increased illumination in the trachea, the display signal processing software can determine the position of the entrance to the trachea, and can selectively enable the intubation tube to be directed into the trachea.

[0026] However, as in all such tracheal imaging systems, there exists the problem that the illumination sensed internally within the patient's throat region, can vary considerably because any cross-sectional population of patients will have a variety of neck sizes and skin colors. These will range from the small, thin, baby's neck, which has very little light absorption ability and therefore will have a very high intra-airway intensity level, to the thick neck of, for instance, an overweight, adult patient, where the illumination penetrating to the larynx region and hence to the image sensor, will be substantially lower. The illuminating device and power level used for the baby would be almost useless for performing the procedure on the large adult patient. In order to overcome this problem, the system described in US 5,560,351 has a light intensity auto-gaining feature, in which a feedback loop is established between the level of light detected by the endoscopic intubation tube sensor electronic circuitry, and the light level applied from the light source unit to the outside of the patient's throat. As indicated in US 5,560,351, in order to influence light source power, the electronic circuitry 25 and the light source unit 21 must be electronically linked, as shown by the electronic communication cable connection 26 in Fig. 2.

[0027] A further need for controlled adjustment of the illumination level in such a system is because of the change in sensed illumination as the intubation tube is moved down the patient's throat. In order to maintain a reasonable level of sensed illumination from the externally located source, and also in order to effectively discriminate the sensed illumination from the external source from any illumination internally provided by the illumination system of the intubation tube endoscope, the externally emitted illumination should be changed to compensate for changes in the optical transmission through the neck cartilage and tissue to the viewing lens of the endoscope, as it moves down the throat.

[0028] Reference is now made to Fig. 3, which schematically shows the system architecture of the prior art intubation system of the type shown in Fig. 2. The externally applied light source 30 delivers its illumination through the patient's tissues, as indicated by the arrow 31, to the region of the trachea/esophagus bifurcation. The endoscopic detector 32 of the endotracheal intubation tube images the inside of the patient's throat, and conveys these images, which could be in the form of a video stream, to the electronic display and processing system 33, which can include display and signal processing hardware and software, for outputting such a video stream to a display unit 34 for view by the user 35. In addition, this electronic unit can include a user interface 36, by means of which the user can control the display function by inputting 37 commands back to the electronic system. After processing the received image intensities, and any user inputs from, the user interface, the electronic system 33, is programmed to send a feedback signal 38 to the light source 30, in order to control the level of the external illumination applied to the patient's throat. The system is thus complex, requiring the use of its own dedicated sensing and illumination units, connected electronically so that they will operate correctly together.

[0029] Reference is now made to Fig. 4A, which illustrates schematically an exemplary implementation of the novel intubation illumination system of the present disclosure. The present system differs from that shown in the above mentioned prior art, in that the illumination is supplied by a battery powered, stand-alone light source unit 40, which can most conveniently be in the form of a patch, applied adhesively to the external throat region of the patient opposite the trachea/esophagus bifurcation, such that the illumination 44 emitted by the patch, is directed internally towards the patient's airway. The illumination patch can be held in position either by an adhesive sticky pad, or by means of a strap, or by any other means which will hold the source in position on the patient's throat. The patch can be simply constructed, containing in its simplest implementation, no more than a battery, an illumination source such as one or more LED's, and a power supply for providing the current for the LED's. Because of this simple and low cost structure, the patch can be manufactured to be disposable, such that its use becomes extremely simple. The patch may be applied to the patient's throat, and once the intubation has been completed, it can be removed and discarded. For such a disposable illumination patch, a battery of low capacity may be used, capable of supplying power to the light

source only for the duration of one intubation procedure, or somewhat more for safety considerations. The illumination patch is adapted to emit a constant level of average light output, and can thus be completely independent of any input signals from other electronic control units. The wavelength of the illumination 44 emitted by the light source 40 can conveniently be in the range of the visible to near infra-red, which is a range which has good transmission through the tissues of the patient's neck, and to which silicon photo-detector arrays, whether CCD or CMOS, have good sensitivity. Such Si camera arrays are preferable because of their low cost and wide availability. The VIS-NIR wavelengths most typically used for implementing the systems of the present disclosure, range from approximately 0.4 to 1.4 μm, though wavelengths outside of this range may also be possible.

[0030] Fig. 4B is a schematic drawing of an exemplary embodiment of such a disposable illumination patch 40, showing the battery 41, electronic circuitry 42 for generating the modulated drive current for the illumination source, and an illumination source, in this case shown as arrays of light emitting diodes 43, emitting their illumination 44. Although for the purposes of showing its internal construction, the disposable illumination patch 40 of Fig. 4B is shown as a planar unit, it is to be understood that it is most conveniently constructed of a flexible material, so that it can conform to the profile of the patient's neck region to which it is applied, and be wrapped around that profile. The patches may also be supplied in a range of sizes and output power, to more readily match the physical size and physiology of different patients.

[0031] However, regardless of suitability of the size of the patch used, in order for the system to be able to handle the different internally collected levels of airway illumination that could arise from application of an external illumination source having a fixed intensity output level, the imaging module must be able to process and display the internal view of the patient's glottal region at an intensity that can be comfortably viewed by the medical personnel administering the intubation, or readily used by any automatic guidance procedures that require a processable image for implementation of the procedure. Therefore, the imaging module should have a system by which the level of light of the imaged frames of the patient's airways can be controlled. However, in order not to depart from the primary concept of the use of a disposable low-cost illumination patch, the imaging module should operate completely independently from the patch, and have no connection thereto. In order to achieve this, in an exemplary implementation of such an intensity control system, the patch is constructed to emit modulated illumination, at a predetermined modulation rate, and the detection system is adapted to detect the modulated illumination penetrating to the patient's airway, and to adjust the level of the output image for display and processing by phase manipulation and/or gating of the received modulated signal.

[0032] Reference is now made to Fig. 5, which schematically shows the system architecture of the intubation system of the present application, displayed in a similar manner to that shown in Fig. 3 for prior art systems. The externally applied light source 50 is a battery powered passive light source, which can conveniently be disposable after use. The light output 51 is modulated, passes into the patient's glottal region, and is imaged by a detector unit 52, which transfers the video stream to the electronic display and processing system 53. The system differs from that shown in Fig. 3, in that there is no feedback or connection from the electronic display and processing system 53 to the externally applied light source 50. Adjustment 58 of the displayed light intensity is generated either by an auto-gain feedback system within the electronic display and processing system 53, or by user preferences 56, applied by the user 55 as he/she views the images of the intubation on the display 54 as the intubation proceeds. Adjustment of the apparent illumination level, as seen as the displayed light intensity, is achieved entirely within the processing system 53, as indicated by the arrow 58. The user can thus control the intensity of that part of the image arising from the externally applied illumination during the intubation procedure to the level desired for maximum clarity, without communicating either physically or wirelessly with the external battery powered passive light source, which remains completely independent of the detection, control and display electronic units.

[0033] An important difference from the prior art systems is that in the system of the present disclosure, the applied external light source 50 transmits a predetermined and fixed light level, which is modulated in order to be able to perform the intensity manipulation of the displayed images, and is completely independent and unconnected to the electronic display and processing system 53. This is one of the features that enables the external light source 50 to be made as a low-cost and disposable item.

[0034] The detection and image processing system may function by applying known image processing techniques to separate those parts of the images of the video frames arising from the modulated illumination coming from the external source, from those parts of the images of the video frames arising from the internally applied illumination coming from the endotracheal tube illumination system. By this means it becomes possible to control the comparative level of these two illumination components, and in particular to maintain the modulated illumination emerging from the trachea at a level which enables ready identification of the trachea. In addition to providing the user with a simpler and more readily controllable image display for use in manually guided intubation procedures, this technique may also enable possible automatic guidance of the endotracheal tube into the trachea, with minimal or no user assistance.

[0035] One such common image processing technique uses a Fast Fourier Transform (FFT) algorithm to extract any components of the original images detected at the

modulation frequency, and to create from these components, a separate image of the modulated illumination, which can then be used as emphasized features overlaid on the conventional for the imaged frames detected by the endotracheal tube video display system. Such an algorithm requires knowledge of the modulation frequency of the externally applied illumination source, but since the standard video frame rates are low, typically no more than a few tens of Hz, modulation frequencies of between 0.5 Hz and 60 Hz can be typically used in this situation. The bandwidth of any FFT algorithm can therefore readily accommodate such a low frequency, and the pre-determined modulation frequency can be closely tracked. Furthermore, the FFT algorithm is sufficiently fast to enable signal processing to the performed in real-time on each frame of the video stream. Eulerian video magnification can be used as another method of delineating the time varying components of the sensed illumination arising from the externally applied modulated light from the constant or slowly varying background illumination from inside the patient's throat regions.

[0036] Other possible methods of processing the image data are based on identifying the phase of the modulation in the images and to separate the image into its two component parts - one that is in-phase with the external light source, where light originated from the external light source will be seen with maximal intensity, and one which is out-of-phase with the external light source, where light originated from the external light source will be seen with minimal intensity or will not be seen at all. Another method based on phase manipulation, is to subtract images generated when the externally modulated light source is at its maximal or ON intensity from the images generated when the externally modulated light source is at its minimal or OFF intensity state.

[0037] In order to illustrate how these latter two image processing methods operate, reference is now made respectively to Figs. 6A to 6G and to Figs. 7A to 7E, which are time based graphs of the sensed illumination, I, displayed by the endoscopic viewing system, as a function of elapsed time, t. The graphs of 6A-6G and 7A-7E are drawn using square-wave pulse modulation, since it is simpler to expound the procedure thus, but it is to be understood that any form of modulation, such as sinusoidal modulation, can equally well be used. The modulation period of the external illumination generated by the throat patch is given by T, and the detected illumination intensity from the internal illumination, is designated by the letter i, while that arising from the external illumination is designated by the letter e. The time graphs illustrate two different ways of controlling the imaged intensity, either for display to the user or for use as an input to any other control feature such as automatic guidance, without the need for any connection, physical or wireless to the throat patch in order to change the apparent illumination level emitted from the throat patch, as displayed or analyzed by the system.

[0038] Reference is first made to Figs. 6A to 6G, which illustrate a method based on phase sensitive detection techniques. Fig. 6A shows the combined output of the internal and external illumination detected by the image sensor. The total illumination is composed of the modulated external illumination e riding on top of the constant internal illumination i. Fig. 6B shows the time trace of a periodic sampling gate applied to the detected illumination of Fig. 6A, the gate temporal profile having the same frequency f = 1/T as the external modulated illumination, and being in phase with it. It is to be understood that this sampling process can be performed either by means of a sampling gate implemented in the imaging hardware, or by means of a virtual sampling gate implemented by the image processing algorithms operating on the imaging data. Additionally, although according to the Nyquist sampling theory, in order to accurately detect an unknown modulated light signal, it is necessary to sample it at a frequency at least twice the modulation frequency, if the modulation frequency is known, either by knowledge of the predetermined characteristics of the external illumination source, or if not, by a preliminary calibration step (which does then need to use the Nyquist criterion), this requirement is unnecessary, and only the gating mechanism for selection of the sampled signals at the modulation frequency is considered to explain this method. The method by which phase synchronization is achieved, when the external modulation is free-running and has no electronic connection with the display system, is described hereinbelow. The resulting signal output from the sampling profile shown in Fig. 6B is shown in Fig. 6C, where a signal is shown representing the total illumination i+e, and in phase with the external modulation of the patch source.

[0039] Reference is now made to Fig. 6D, which shows the time trace of the periodic sampling gate of Fig. 6B, but this time with the sampling gate in anti-phase with the external modulated illumination. The resulting signal output is shown in Fig. 6E, where it is seen that since the sampling gate is OFF during the ON periods of the external illumination, the external illumination is completely suppressed, and only the internal illumination, i, is displayed. Thus, by adjusting the phase of the sampling gate relative to the phase of the external modulation illumination, it is possible to adjust the level of the external illumination sensed by the display system. Thus, for instance, in Fig. 6F, the sampling gate is temporally positioned, such that it is 90° out of phase with the externally applied modulation illumination, and the result is intermediate between full suppression and full display of the external illumination, as shown in Fig. 6G.

[0040] In order to implement such a phase sensitive detection mode, it is necessary for the display system to be able to synchronize to the phase of the external modulation illumination, which, being generated in a completely independent unit, cannot be measured by direct electronic connection to the source modulation driver. Such synchronization can be achieved by simply varying the phase delay τ of the sampling gate, while observing

the total intensity of the video stream images detected. When the total intensity is at a maximum, that is a sign that the sampling gate timing is exactly in phase with the external modulation.

[0041] One of the disadvantages of the phase sensitive detection method shown in Figs. 6A to 6G is that it is impossible to eliminate the effect of the internally generated illumination from the endoscopic source, though of course it is possible to reduce the level of that illumination if necessary. Reference is therefore now made to Figs. 7A to 7E, which illustrate an alternative method of controlling the displayed image intensity, in such a manner that the external intensity can be rendered to be the major or even the only component shown in the display system. This method operates by use of video frame manipulation, including addition or subtraction of frame sequences. Fig. 7A is equivalent to Fig. 6A, and shows the combined output of the internal and external illumination detected by the image sensor system. Fig. 7B is equivalent to Fig. 6C, and shows the displayed output for in-phase detection of the illumination. Fig. 7C is equivalent to Fig. 6E, and shows the display outputted for anti-phase detection of the illumination, which corresponds to the internal illumination, i, only. The image video frame streams can now be time manipulated by the system algorithm, in order to achieve the desired output. Thus, in Fig. 7D, the internal illumination signal of Fig. 7C has been shifted by 180°, so that it is now in the same phase as the in-phase detected illumination shown in Fig. 6B. If the signal train of Fig. 7D is now subtracted from that of Fig. 7B, the resulting output shown in Fig. 7E is a video train, representing the external illumination only. By varying the phase shift applied to the video train of Fig. 7D, before subtraction from that of Fig. 7B, it becomes possible to vary the comparative percentages of the internal and external illumination shown in the displayed images. Alternatively, attenuation can be applied to either the internal video data stream, as represented by Fig. 7D, or the external video data stream, as represented by Fig. 7E, in order to achieve the optimum illumination combination for the intubation procedure. If an auto gain feature is provided in the display control, then any of these attenuation or phase adjustments can be performed automatically, to provide a loop closing illumination level.

[0042] Using the intubation guidance system described in Figs. 5 to 7E, it is possible readily to implement an automatic intubating system, using the enhanced image of the modulated illumination emitted from the position of the trachea as the target for the endotracheal tube.

[0043] In such a system, the image is processed in order to isolate or increase the modulated light originated from the external source, and to separate it from the "background" noise which did not originate from the modulated external source. The processing of the image can be done by using the system and algorithms described hereinabove, or by any other methods. In addition, the area in the image where the received intensity of the modulated light is maximal, can be calculated in order to define the preferred direction for the automatic guidance and movement of a mechanical or robotic conduit that carries the intubation tube towards the trachea. In one possible implementation, the tip of the conduit is guided to automatically turn towards the maximum modulated light intensity as calculated by the software, whereas the movement of tip or of the entire conduit forward or backward within the patient's throat may be performed manually by the user. According to a further embodiment, motion of the tip or of the entire conduit forward or backward can also be automatically controlled by the system, so that the endotracheal the tube can be automatically located within the trachea.

[0044] It is appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of various features described hereinabove as well as variations and modifications thereto which would occur to a person of skill in the art upon reading the above description and which are not in the prior art.

Claims

1. A system for performing guided tracheal intubation on a subject, comprising:

   - an autonomous light sources (40, 50) adapted to provide a modulated illumination output, the modulated illumination output having a predetermined maximal intensity and being periodically modulated between a maximal intensity state and a minimal intensity state at a predetermined frequency, the autonomous light source being_adapted to be externally applied to the neck of the subject in the region of the subject's larynx;
   - an optical sensing system (52) adapted to receive a stream of image data from an endotracheal placement device within the throat of the subject, the optical image data including data relating to the modulated illumination output which has penetrated the trachea of the subject; and
   - a control system (53) adapted to be provided with the predetermined frequency of the modulated illumination output and adapted to perform signal processing on the received stream of image data based on the predetermined frequency, and adapted to generate a modified stream of image output data having an adjusted apparent sensed intensity of the modulated illumination output,
   - wherein the autonomous light source is completely independent and unconnected to the control system and does not receive a feedback

signal from the control system.

2. The system according to claim 1, wherein the signal processing utilizes phase manipulation of the optical image data, in order to discriminate between the modulated illumination which has penetrated the trachea of the subject, and illumination applied internally to the subject's larynx region from the endotracheal placement device.

3. The system according to claims 1 or 2, wherein the apparent sensed intensity of the modulated illumination output is adjustable by a user of the system during the guided tracheal intubation.

4. The system according to one of the claims 1 to 3, wherein the apparent sensed intensity of the modulated illumination output is adjusted automatically to provide a predetermined level of contrast in images generated from the image data.

5. The system according to one of the claims 1 to 4, wherein the autonomous modulated light source comprises at least one battery, at least one light emitter, and a circuit for powering the at least one light emitter.

6. The system according to one of claims 1 to 5, wherein the at least one light emitter is a light emitting diode.

7. The system according to one of claims 1 to 6, wherein the illumination has a wavelength within the range of from 0.4 micrometers to 1.4 micrometers.

8. The system according to one of claims 1 to 7, wherein the autonomous modulated light source comprises either an adhesive element or a strap, for application to the neck of the subject in the region of the subject's larynx.

9. The system according to one of claims 1 to 8, wherein the autonomous modulated light source is adapted to be disposable after a single use.

10. The system according to one of claims 1 to 9, wherein the image data is sampled at a frequency at least twice as high as the frequency of the modulated illumination output.

11. The system according to one of claims 1 to 10, wherein the modulated illumination output is square wave or sinusoidally modulated.

12. The system according to one of claims 1 to 11, wherein the stream of sampled image data is a video stream of images.

13. The system according to claim 5, wherein a patch comprises the autonomous modulated light source and wherein the patch is adapted to be externally applied to the neck of the subject.

14. The system according to claim 1, wherein the maximal intensity state is an ON state and the minimal intensity state is an OFF state.

Patentansprüche

1. System zum Durchführen einer geführten Trachealintubation bei einer Testperson, das Folgendes aufweist:

   - eine autonome Lichtquelle (40, 50), die dazu ausgebildet ist, eine modulierte Lichtausgabe bereitzustellen, wobei die modulierte Lichtausgabe eine vorbestimmte maximale Intensität aufweist und periodisch moduliert wird, und zwar zwischen einem Zustand maximaler Intensität und einem Zustand minimaler Intensität bei einer vorbestimmten Frequenz, wobei die autonome Lichtquelle dazu ausgebildet ist, extern an dem Hals der Testperson angewendet zu werden, und zwar in dem Kehlkopfbereich der Testperson;
   - ein optisches Messsystem (52), das dazu ausgebildet ist, einen Strom von Bilddaten von einer endotrachealen Anordnungsvorrichtung innerhalb des Rachens der Testperson zu empfangen, wobei die optischen Bilddaten Daten beinhalten, die die modulierte Lichtausgabe betreffen, die in die Luftröhre der Testperson eingedrungen ist; und
   - ein Steuersystem (53), das dazu ausgebildet ist, mit der vorbestimmten Frequenz der modulierten Lichtausgabe versorgt zu werden und das dazu ausgebildet ist, Signalverarbeitung bei dem empfangenen Strom von Bilddaten durchzuführen, und zwar basierend auf der vorbestimmten Frequenz, und das dazu ausgebildet ist, einen modifizierten Strom von Bildausgangsdaten zu generieren, der eine angepasste scheinbar wahrgenommene Intensität der modulierten Lichtausgabe aufweist,
   - wobei die autonome Lichtquelle vollständig unabhängig von und nicht verbunden ist mit dem Steuersystem und kein Rückgabesignal von dem Steuersystem empfängt.

2. System gemäß Anspruch 1, wobei die Signalverarbeitung Phasenmanipulation der optischen Bilddaten verwendet, um zwischen dem modulierten Licht, das in die Luftröhre der Testperson eingedrungen ist, und dem Licht zu unterscheiden, das intern an dem Kehlkopfbereich der

Testperson von der endotrachealen Anordnungsvorrichtung angewendet wird.

3. System gemäß Anspruch 1 oder 2, wobei die scheinbar wahrgenommene Intensität der modulierten Lichtausgabe von einem Benutzer des Systems während der geführten Trachealintubation einstellbar ist.

4. System gemäß einem der Ansprüche 1 bis 3, wobei die scheinbar wahrgenommene Intensität der modulierten Lichtausgabe automatisch angepasst wird, um ein vorbestimmtes Kontrastniveau bei Bildern bereitzustellen, die aus den Bilddaten generiert worden sind.

5. System gemäß einem der Ansprüche 1 bis 4, wobei die autonome modulierte Lichtquelle Folgendes aufweist: mindestens eine Batterie, mindestens einen Lichtemitter, und eine Schaltung zum Antreiben des mindestens einen Lichtemitters.

6. System gemäß einem der Ansprüche 1 bis 5, wobei der mindestens eine Lichtemitter eine Leuchtdiode ist.

7. System gemäß einem der Ansprüche 1 bis 6, wobei das Licht eine Wellenlänge innerhalb eines Bereichs von 0,4 Mikrometer bis 1,4 Mikrometer aufweist.

8. System gemäß einem der Ansprüche 1 bis 7, wobei die autonome modulierte Lichtquelle entweder ein klebendes Element oder einen Gurt aufweist, und zwar zur Anwendung am Hals der Testperson in dem Kehlkopfbereich der Testperson.

9. System gemäß einem der Ansprüche 1 bis 8, wobei die autonome modulierte Lichtquelle dazu ausgebildet ist, nach Einmalgebrauch wegwerfbar zu sein.

10. System gemäß einem der Ansprüche 1 bis 9, wobei die Bilddaten bei einer Frequenz abgetastet werden, die mindestens doppelt so hoch ist wie die Frequenz der modulierten Lichtausgabe.

11. System gemäß einem der Ansprüche 1 bis 10, wobei die modulierte Lichtausgabe rechteckwellen- oder sinusförmig moduliert wird.

12. System gemäß einem der Ansprüche 1 bis 11, wobei der Strom abgetasteter Bilddaten ein Videostrom von Bildern ist.

13. System gemäß Anspruch 5, wobei ein Pflaster die autonome modulierte Lichtquelle aufweist und wobei das Pflaster dazu ausgebildet ist, extern am Hals der Testperson angewendet zu werden.

14. System gemäß Anspruch 1, wobei der Zustand maximaler Intensität ein EIN-Zustand und der Zustand minimaler Intensität ein AUS-Zustand ist.

Revendications

1. Système pour exécuter une intubation trachéale guidée sur un sujet, comprenant :

- une source de lumière autonome (40, 50) adaptée pour fournir une illumination modulée en sortie, l'illumination modulée en sortie ayant une intensité maximale prédéterminée et étant périodiquement modulée entre un état d'intensité maximum et un état d'intensité minimum à une fréquence prédéterminée, la source de lumière autonome étant adaptée à être appliquée par voie externe sur le cou du sujet dans la région du larynx du sujet ;
- un système détecteur optique (52) adapté pour recevoir un flux de données d'imagerie depuis un dispositif de mise en place endotrachéal à l'intérieur de la gorge du sujet, les données d'imagerie optique incluant des données en relation à l'illumination modulée en sortie qui a pénétré la trachée du sujet ; et
- un système de commande (53) adapté pour être alimenté avec la fréquence prédéterminée de l'illumination modulée en sortie et adapté à effectuer un traitement de signal sur le flux de données d'imagerie reçues sur la base de la fréquence prédéterminée, et adapté à générer un flux modifié de données d'imagerie en sortie ayant une intensité détectée apparente ajustée de l'illumination modulée en sortie,
- dans lequel la source de lumière autonome est complètement indépendante et n'est pas connectée au système de commande, et ne reçoit pas de signal de rétroaction depuis le système de commande.

2. Système selon la revendication 1, dans lequel le traitement de signal utilise une manipulation de phase des données d'imagerie optiques, afin de faire une discrimination entre l'illumination modulée qui a pénétré la trachée du sujet et l'illumination appliquée par voie interne à la région du larynx du sujet depuis le dispositif de mise en place endotrachéal.

3. Système selon les revendications 1 ou 2, dans lequel l'intensité détectée apparente de l'illumination modulée en sortie est ajustable par un uti-

lisateur du système pendant l'intubation trachéale guidée.

4. Système selon l'une des revendications 1 à 3, dans lequel l'intensité détectée apparente de l'illumination modulée en sortie est ajustée automatiquement pour fournir un niveau de contraste prédéterminé dans les images générées à partir des données d'imagerie.

5. Système selon l'une des revendications 1 à 4, dans lequel la source de lumière modulée autonome comprend au moins une batterie, au moins un émetteur de lumière, et un circuit pour alimenter ledit au moins un émetteur de lumière.

6. Système selon l'une des revendications 1 à 5, dans lequel ledit au moins un émetteur de lumière est une diode émettrice de lumière.

7. Système selon l'une des revendications 1 à 6, dans lequel l'illumination a une longueur d'onde dans la plage de 0,4 μm à 1,4 μm.

8. Système selon l'une des revendications 1 à 7, dans lequel la source de lumière modulée autonome comprend soit un élément adhésif soit un ruban, pour l'application sur le cou du sujet dans la région du larynx du sujet.

9. Système selon l'une des revendications 1 à 8, dans lequel la source de lumière modulée autonome est adaptée à être jetée après une utilisation unique.

10. Système selon l'une des revendications 1 à 9, dans lequel les données d'imagerie sont échantillonnées à une fréquence au moins deux fois aussi élevée que la fréquence de l'illumination modulée en sortie.

11. Système selon l'une des revendications 1 à 10, dans lequel l'illumination modulée en sortie est modulée avec une onde carrée ou une onde sinusoïdale.

12. Système selon l'une des revendications 1 à 11, dans lequel le flux des données d'imagerie échantillonnées est un flux d'images vidéo.

13. Système selon la revendication 5, dans lequel un "patch" comprend la source de lumière modulée autonome et dans lequel le patch est adapté à être appliqué par voie externe sur le cou du sujet.

14. Système selon la revendication 1, dans lequel l'état d'intensité maximum est un état de "MARCHE" et l'état d'intensité minimum est un état d'"ARRÊT".

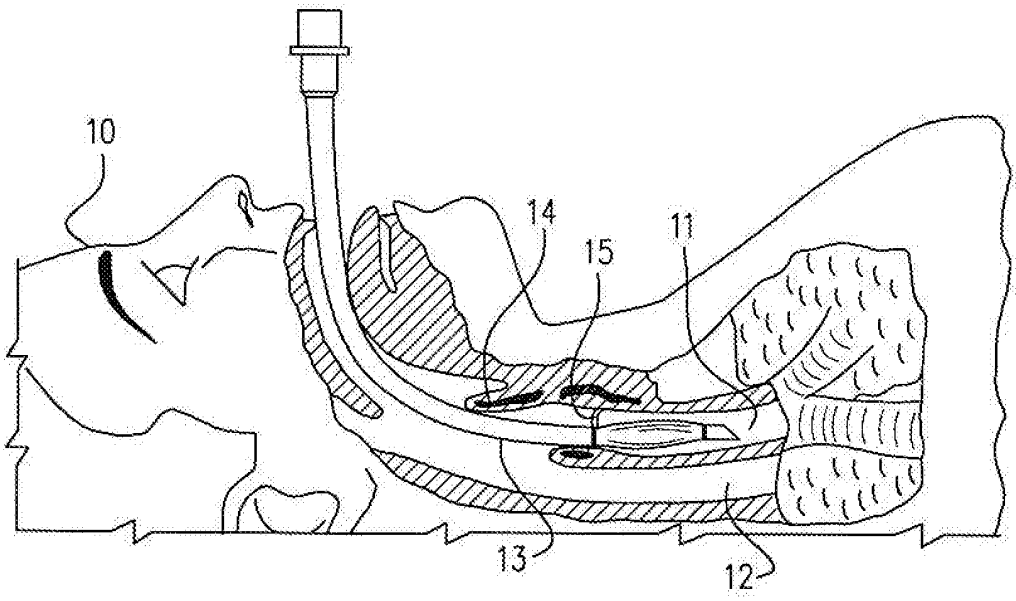

FIG. 1

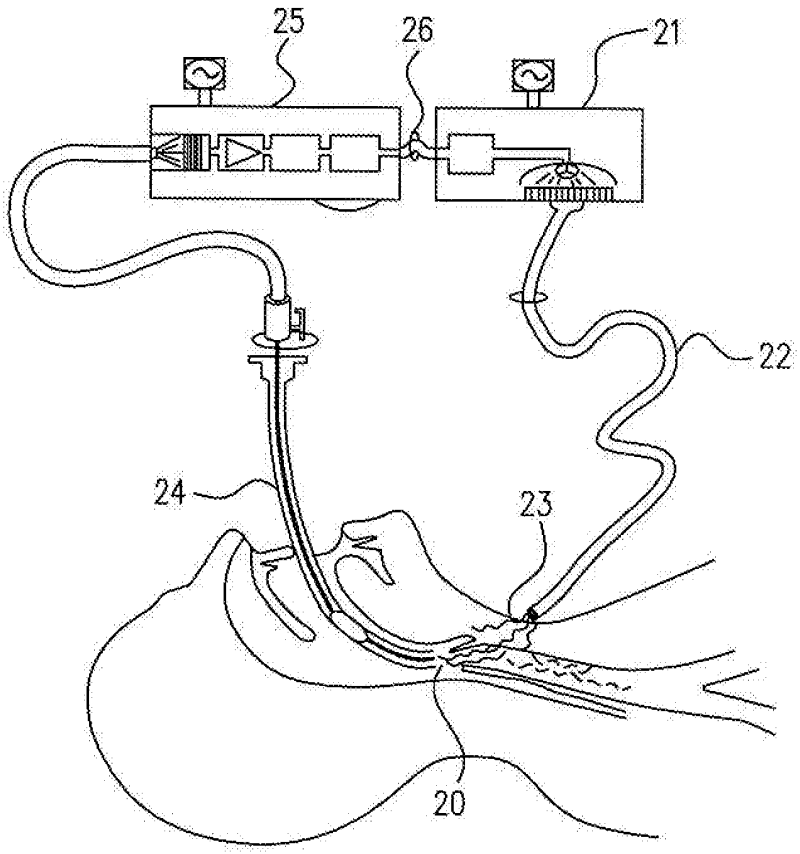

FIG. 2
(PRIOR ART)

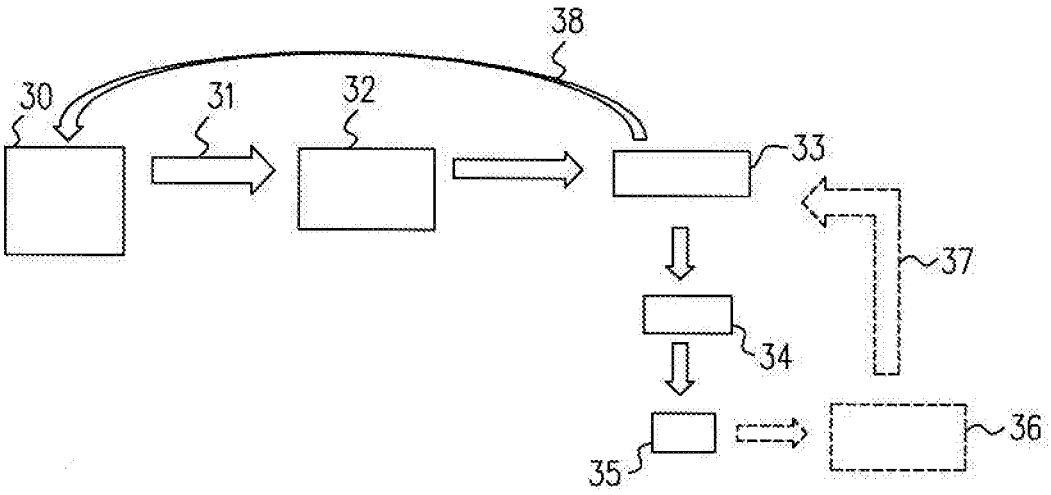

FIG. 3
(PRIOR ART)

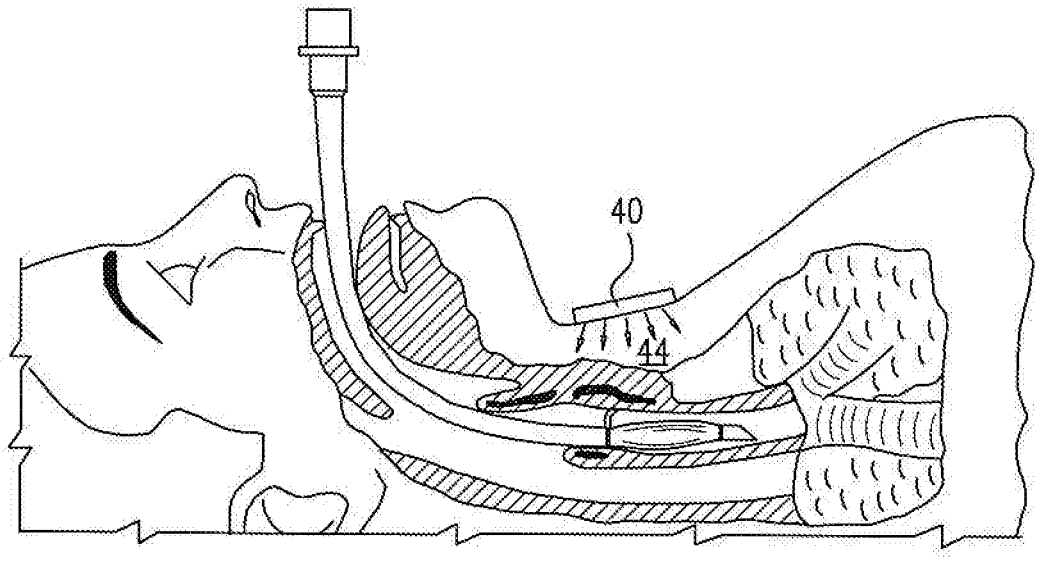

FIG. 4A

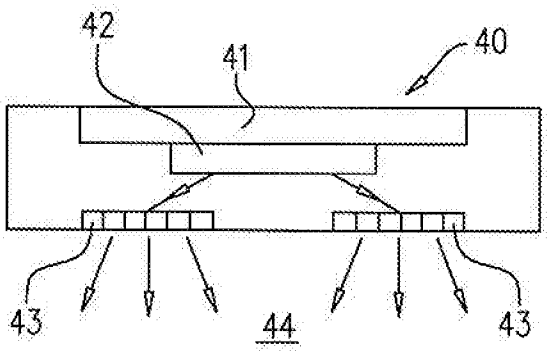

FIG. 4B

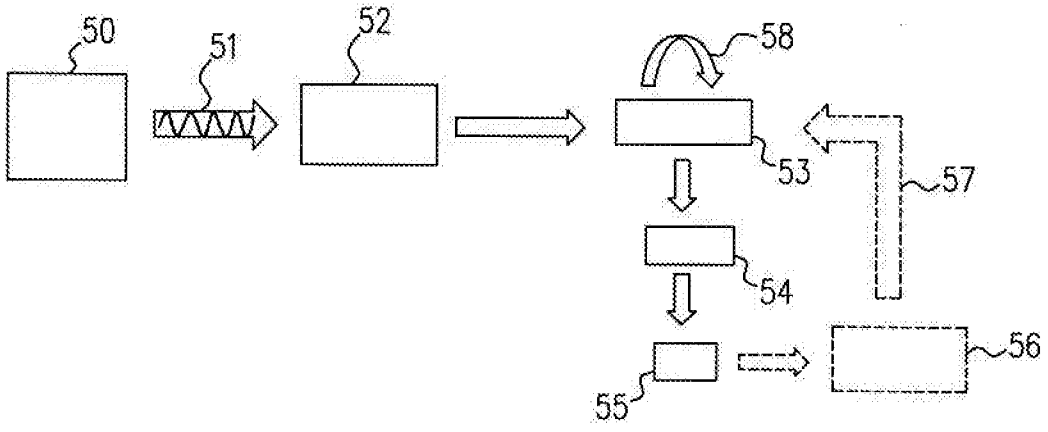

FIG. 5

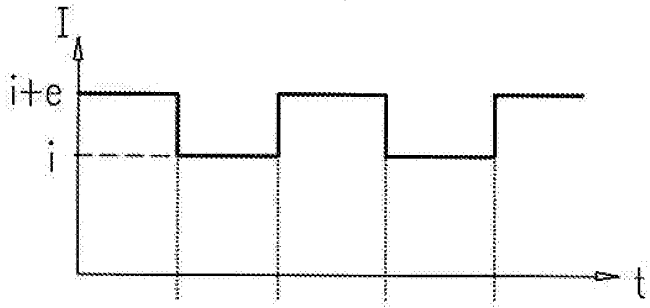

FIG. 6A

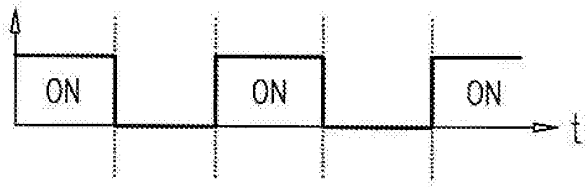

FIG. 6B

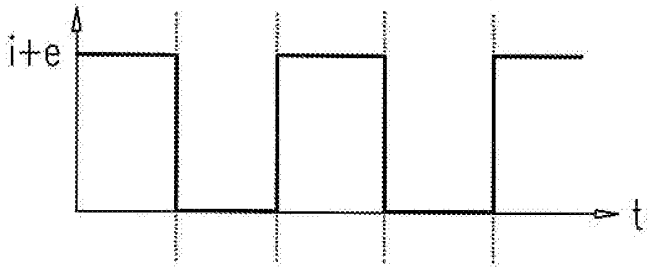

FIG. 6C

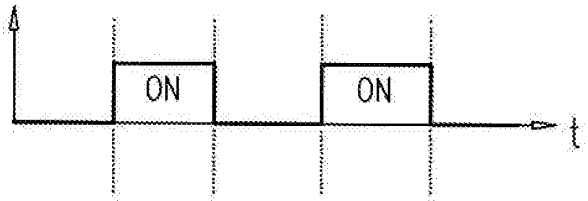

FIG. 6D

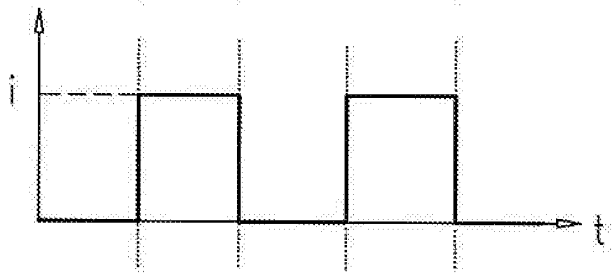

FIG. 6E

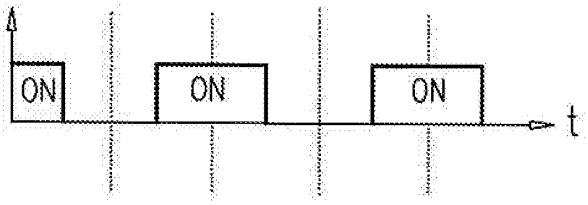

FIG. 6F

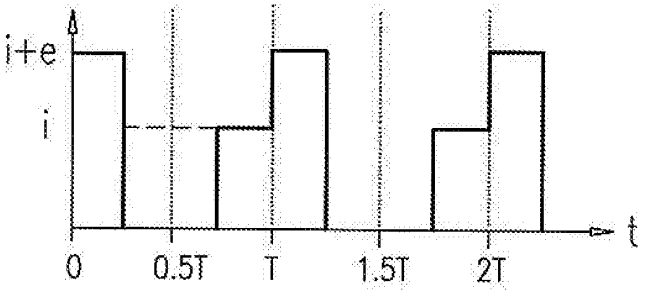

FIG. 6G

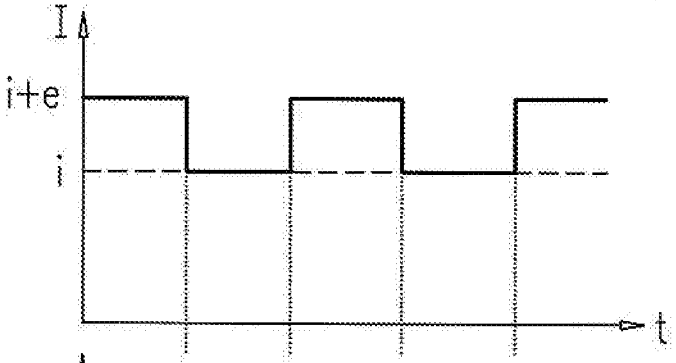

FIG. 7A

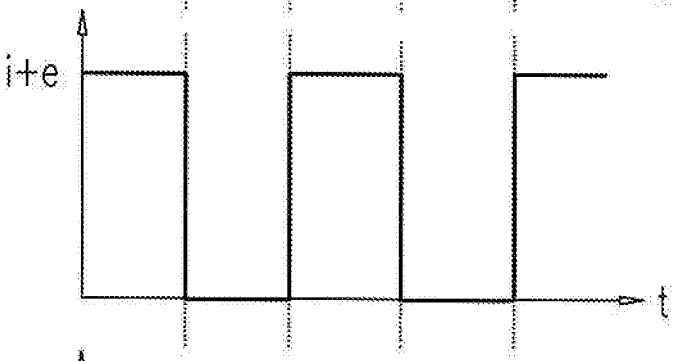

FIG. 7B

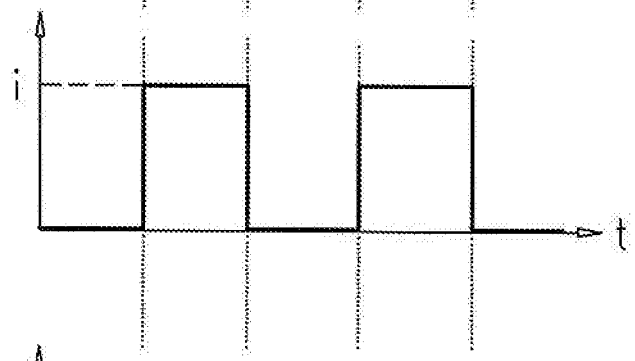

FIG. 7C

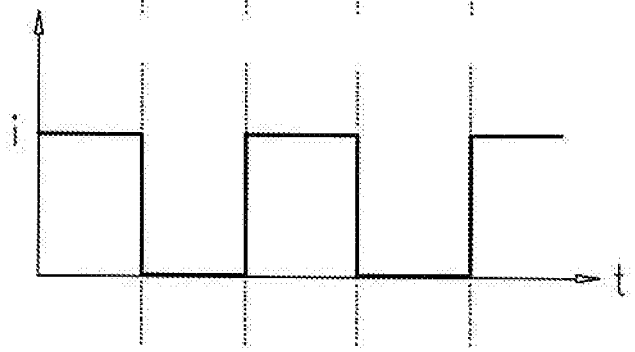

FIG. 7D

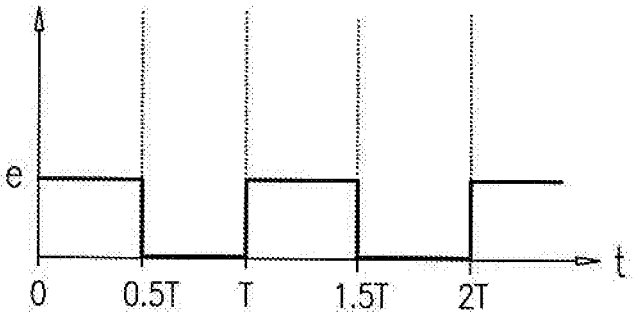

FIG. 7E

REFERENCES CITED IN THE DESCRIPTION

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- US 20110178369 A **[0004]**
- US 5560351 A **[0025] [0026]**

专利名称(译)	引导气管插管系统		
公开(公告)号	EP2996549B1	公开(公告)日	2018-03-07
申请号	EP2014732408	申请日	2014-05-16
[标]申请(专利权)人(译)	耶路撒冷希伯来大学伊森姆研究发展公司		
申请(专利权)人(译)	YISSUM研究开发公司有限公司耶路撒冷希伯来大学. HADASIT医学研究服务和发展有限公司.		
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发明人	HAYUT, ITAI FRIED, ELCHANAN NAHMIAS, YAAKOV WEISS-SADAN, TOMMY SHREM, ARIEL		
IPC分类号	A61B5/00 A61M16/04 A61B1/04 A61B1/06		
CPC分类号	A61B1/00165 A61B1/04 A61B1/0661 A61B1/2676 A61B2560/06 A61B2576/02 A61M16/0488 A61M2210/1032 A61B1/00009 A61B1/267 A61B1/06		
代理机构(译)	TRINKS，OLE		
优先权	61/824015 2013-05-16 US 61/950413 2014-03-10 US		
其他公开文献	EP2996549A2		
外部链接	Espacenet		

摘要(译)

使用自主调制光源的引导气管插管系统，以恒定水平输出调制照明，并外部施加到受试者的喉部区域。光学成像系统从受试者的喉咙内接收视频流，包括来自受试者气管的调制照明。显示控制系统对图像的调制内容执行信号处理，并输出那些图像的帧，其中可以控制来自气管的强度照度，而不需要改变来自调制光源的照明输出。光源与系统的其余部分没有连接，并且只需要包含电池，电源电路和光源。因此，它可以是低成本的并且可以制成一次性的，例如以施加到受试者颈部的粘合剂贴片的形式。

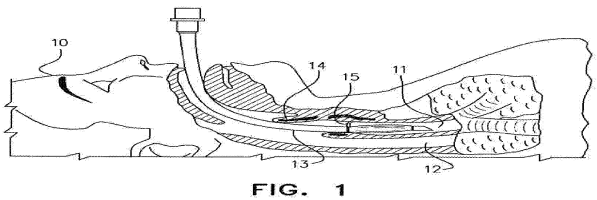

FIG. 1

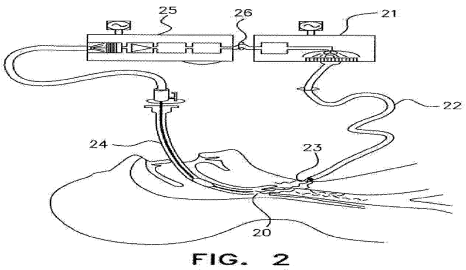

FIG. 2
(PRIOR ART)