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WO-A1-2013/045506
WO-A1-2013/120774
US-A1- 2003 076 408
US-A1- 2006 071 950
US-A1- 2011 118 700
US-A1- 2011 295 215
US-A1- 2012 134 588
US-A1- 2013 197 445
US-A1- 2014 005 950
Piksoft Inc: "Perfect OCR: document scanner with high quality OCR on the App Store on iTunes", , 24 October 2011 (2011-10-24), XP055176793, Retrieved from the Internet: URL:https://itunes.apple.com/us/app/perfect-ocr-document-scanner/id363095388?mt=8 [retrieved on 2015-03-16]

Fortsættes ...

DESCRIPTION

Field of the Invention

[0001] The present invention relates to data collection from a medicament delivery device. In particular, the present invention relates to a method and a data collection system for recording a medicament dose.

Background of the Invention

[0002] A variety of diseases exists that require regular treatment by injection of a medicament. Such injection can be performed by using injection devices, which are applied either by medical personnel or by patients themselves. As an example, type-1 and type-2 diabetes can be treated by patients themselves by injection of insulin doses, for example once or several times per day. For instance, a pre-filled disposable insulin pen can be used as an injection device. Alternatively, a re-usable pen may be used. A re-usable pen allows replacement of an empty medicament cartridge by a new one. Either pen may come with a set of one-way needles that are replaced before each use. The insulin dose to be injected can then for instance be manually selected at the insulin pen by turning a dosage knob and observing the actual dose from a dosage window or display of the insulin pen. The dose is then injected by inserting the needle into a suited skin portion and pressing an injection button of the insulin pen.

[0003] To be able to monitor insulin injection, for instance to prevent false handling of the insulin pen or to keep track of the doses already applied, it is desirable to measure information related to a condition and/or use of the injection device, for example, one or more of the injected insulin type, dose and timing of the injection, in a manner that is reliable and accurate.

[0004] Data collection techniques may also be used for purposes other than monitoring insulin injections. For example, data may be collected in order to monitor injections of other medicaments, other medical activities, such as the taking of tablet medication by a patient or infusions, or for non-medical purposes, such as the monitoring of equipment and/or its operation in a home or industrial environment for safety reasons. US 2013/197445 and WO 2013/120774 disclose data collection devices. WO 2013/045506 discloses a drug delivery pen that displays information. US 2011/295215 discloses a monitoring device mounted onto a drug delivery device. US 2011/118700 discloses a drug delivery device in which movement of a dosage setting knob is detected. US 2014/005950 discloses the use of mechanical and/or acoustic sensors to detect movement of a dosage knob of a drug delivery device. US 2003/076408 discloses a hand-held device that can scan and analyse images.

Summary

[0005] According to one aspect, there is provided a method of recording a medicament dose using a data collection device, the method including capturing, by a video camera of the data collection device, a video showing a medicament dose indicator of a medicament delivery device, adjusting a scale of an image in said video, adjusting said image for skew of one or more characters displayed on a component of the medicament delivery device in said video, determining the position of at least one of said one or more characters in the image, identifying the at least one character using optical character recognition, and determining a medicament dose indicated by the medicament dose indicator based on a result of said optical character recognition.

[0006] The obtaining of medicament delivery information from a video recording may provide a reliable record and/or monitoring of the administration of medicament to a patient, since it does not rely on specific input from the patient and so may avoid user error and/or user failure to recollect details of an injection.

[0007] The data collection device is a portable electronic device. In particular, the data collection apparatus is a wearable electronic device. Where the data collection device is a device that is commonly available, medicament delivery may be reliably recorded and monitored without requiring specialised, or dedicated, data collection devices. Also, since the user can utilise a device that is familiar to them for data collection, the user may begin to record dosages without having to familiarise themselves, and learn to use, a new device.

[0008] Where the data collection device is a wearable device that is worn on the head of the user, the captured video may correspond approximately to the point of view of a user, increasing the likelihood that the medicament dose indicator will be shown in the captured video.

[0009] The method may comprise determining whether more than one delivery of medicament is recorded in said video. In response to a determination that more than one delivery of medicament is recorded in said video, at least a second medicament dose based on at least one character identified using optical character recognition on at least a second image of said medicament dose indicator in said video may be determined, and an overall medicament dose received by a user determined based on said determined medicament dose and said determined second medicament dose. Alternatively, or additionally, the method may determine whether said more than one delivery of medicament includes one or more prime shots, so that any determined medicament doses associated with a prime shot can be disregarded.

[0010] The method may include obtaining colour information from said image and identifying a type of medicament to be dispensed based on said colour information. The obtaining of colour information may include obtaining a colour balance measurement based on reference colour information provided on the medicament delivery device.

[0011] The medicament delivery device may be an injector pen including a movable

component for selecting said amount of medicament to be dispensed.

[0012] This aspect also provides a computer program comprising computer-readable instructions that, when executed by a processor, causes one or more of the above methods to be performed. Such a computer program may be provided in the form of an "app" for a wearable electronic device or other portable electronic device.

[0013] This aspect further provides a data collection apparatus for recording a medicament dose, comprising a video camera and a processing arrangement configured to capture a video using said video camera, said video including at least one image of a medicament dosage indicator of a medicament delivery device, adjust a scale of said image, adjust said image for skew of one or more characters displayed on a component of the medicament delivery device, determine the position of at least one of said one or more characters in the image, identify the at least one character using optical character recognition and determine a dosage indicated by said medicament dose indicator based on a result of said optical character recognition.

[0014] This aspect also provides a medicament delivery system including such a data collection apparatus and the medicament delivery device.

[0015] The data collection apparatus comprises a wearable electronic device that includes said video camera. Such a wearable electronic device may be configured to be worn on the head of a user, so that the captured video corresponds to the user's point of view. For example, the wearable electronic device may be provided in a form that can be worn by the user in a similar manner to a pair of glasses or sunglasses.

[0016] The apparatus may be configured so that the video camera and processing arrangement are included in the same device, such as a wearable device as discussed above. However, in some embodiments, the video camera may be provided in a device that is configured to transmit the captured video to a computer via a network, such as a wireless local area network, a personal area network, a cellular communication network or the Internet, where the computer comprises said processing arrangement.

[0017] The processing arrangement may be configured to determine whether more than one delivery of medicament is recorded in said video. The processing arrangement may be configured to respond to a determination that more than one delivery of medicament is recorded in said video by determining at least a second medicament dose based on at least one character identified using optical character recognition on at least a second image of said medicament dose indicator in said video and determining an overall dosage received by a user based on said determined medicament dose and said determined second medicament dose. Alternatively, or additionally, the processing arrangement may be configured to respond to such a determination by determining whether said more than one delivery of medicament includes one or more prime shots, so that any determined medicament doses associated with said one or more prime shots can be disregarded.

[0018] The processing arrangement may be configured to identify a colour of at least one component of the medicament delivery device and to determine a type of said medicament based on said colour. In some embodiments, the processing arrangement may be configured to obtain a colour balance measurement based on an image showing reference colour information provided on the medicament delivery device.

Brief Description of the Drawings

[0019] Example embodiments of the invention will now be described with reference to the accompanying figures, of which:

Figure 1a shows an exploded view of a medicament delivery device;

Figure 1b shows a perspective view of a portion of the medicament delivery device of Figure 1a;

Figure 2 is a block diagram of a data collection device according to an embodiment of the invention;

Figure 3 is a flowchart of a data collection method according to an embodiment of the invention;

Figures 4 and 5 each show a portion of a dosage window of the drug delivery device of Figure 1a, with examples of digits that may be displayed;

Figure 6 shows an example of a binarized digits corresponding to digits displayed in the dosage window;

Figures 7 and 8 show diagrammatically further examples of digits that may be displayed in the dosage window; and

Figure 9 shows a further example of digits that may be displayed in the dosage window where a primary digit row contains two digits; and

Figure 10 is a flowchart of a data collection method according to another embodiment of the invention.

Detailed Description

[0020] In the following, embodiments of the present invention will be described with reference to an insulin injection device. The present invention is however not limited to such application and, as noted herein above, may equally well be deployed with injection devices that eject other medicaments, or with other types of medicament delivery devices.

[0021] Figure 1a is an exploded view of an injection device 1 which, in this particular example, represents Sanofi's Solostar(R) insulin injection pen.

[0022] The injection device 1 of Figure 1a is a pre-filled, disposable injection pen that comprises a housing 10 and contains an insulin container 14, to which a needle 15 can be affixed. The needle is protected by an inner needle cap 16 and an outer needle cap 17, which in turn can be covered by a cap 18. An insulin dose to be ejected from injection device 1 can be selected by turning the dosage knob 12, and the selected dose is then displayed via dosage window 13, for instance in multiples of so-called International Units (IU), wherein one IU is the biological equivalent of about 45.5 micrograms of pure crystalline insulin (1/22 mg). An example of a selected dose displayed in dosage window 13 may for instance be 30 IUs, as shown in Figure 1a. It should be noted that the selected dose may equally well be displayed differently.

[0023] The dosage window 13 may be in the form of an aperture in the housing 10, which permits a user to view a limited portion of a number sleeve 70 that is configured to move when the dosage knob 12 is turned. In order to facilitate taking images of the numbers displayed in the dosage window 13, the number sleeve 70 may have a matte surface.

[0024] A label 19 is provided on the housing 10. The label 19 includes information about the medicament included within the injection device, including information identifying the medicament. The information identifying the medicament may be in the form of text. The information identifying the medicament may also be in the form of a colour. For example, the label 19 may have a background, or include a shaded element such as a border having a color that corresponds to a particular type of medicament that is provided in the injection device. Alternatively, or additionally, the label may include a RFID tag or similar device that stores such information.

[0025] One or more parts of the injection device, such as an injection button 11 or the dosage knob 12, may be formed of a material having a colour that corresponds to the medicament. Optionally, a part of an insulin container (not shown) within the injection device 1 may include a colour-coded portion that indicates a medicament type and may be viewable through the dosage window 13. The information identifying the medicament may additionally, or alternatively, be encoded into a barcode, QR code or the like. The information identifying the medicament may also be in the form of a black and white pattern, a colour pattern or shading.

[0026] Turning the dosage knob 12 causes a mechanical click sound to provide acoustic feedback to a user. The numbered sleeve 70 mechanically interacts with a piston in insulin container 14. When needle 15 is stuck into a skin portion of a patient, and then injection button 11 is pushed, the insulin dose displayed in the dosage window 13 will be ejected from injection device 1. When the needle 15 of injection device 1 remains for a certain time in the skin portion after the injection button 11 is pushed, a high percentage of the dose is actually injected into the patient's body. Ejection of the insulin dose also causes a mechanical click sound, which is

however different from the sounds produced when using dosage knob 12.

[0027] Injection device 1 may be used for several injection processes until either insulin container 14 is empty or the expiration date of injection device 1 (e.g. 28 days after the first use) is reached.

[0028] Furthermore, before using injection device 1 for the first time, it may be necessary to perform a so-called "prime shot" to remove air from insulin container 14 and needle 15, for instance by selecting 2 IU of insulin and pressing injection button 11 while holding injection device 1 with the needle 15 upwards. For simplicity of presentation, in the following, it will be exemplarily assumed that the ejected doses substantially correspond to the injected doses, so that, for instance when making a proposal for a dose to be injected next, this dose equals the dose that has to be ejected by the injection device. Nevertheless, differences (e.g. losses) between the ejected doses and the injected doses may of course be taken into account, particularly with regard to a "prime shot".

[0029] Figure 1b is a close-up of the end of the injection device 1. In the particular example shown in Figure 1, a locating rib 71 is located between the viewing window 13 and the dosage knob 12.

[0030] Fig. 2 is a block diagram of a data collection device 20 according to an embodiment of the invention, that may be used to collect data, such as insulin type, dosage and timing of injection, from the injection device 1 of Fig. 1.

[0031] The data collection device 20 is an electronic device, equipped with a built-in video camera 21, and a processing arrangement 22 including one or more processors, such as a microprocessor, a Digital Signal Processor (DSP), Application Specific Integrated Circuit (ASIC), Field Programmable Gate Array (FPGA) or the like. In this particular example, the data collection device 20 is a wearable electronic device, such as a video camera device that may be worn by the user to record images from their point of view, or a computing device that is mounted in a pair of glasses or otherwise worn on the head or body of the user.

[0032] The data collection device 20 also includes memory units 23, 24, including a read-only memory 23 and a random access memory 24, which can store software for execution by the processing arrangement 22. The data collection device 20 also includes communications equipment 25, 26, such as an antenna 25 and a transceiver 26, to permit bi-directional communication with one or more of a cellphone network, a personal area network, a local wireless network or WLAN, and the Internet. The data collection device 20 further includes an input arrangement 27, 28, such as a keypad 27 and/or a microphone 28, and an output arrangement 29, 30, such as a speaker 29 and/or a display 30. In some embodiments, the input arrangement may include provide a keypad 27 in the form of a touch-sensitive element, or "touchpad" or as part of a touch-screen that utilizes some or all of the display 31. The input arrangement may alternatively, or additionally, include a motion sensor arrangement 31, such as one or more accelerometers, for detecting movement of the data collection device 20. The

data collection 20 also includes a communications bus 32 allowing for communication between the video camera 21, processing arrangement 22, memory units 23, 24, communications equipment 25, 26, input arrangement 27, 28, 31 and output arrangement 29, 30.

[0033] The software stored in the memory units 23, 24 of the data collection device 20 includes computer-readable instructions that, when executed by the processing arrangement 22, causes the data collection device 20 to record a video, and to process the video to obtain data regarding the type of medicament in the injection device 1, a dose delivered by the injection device 1 and, optionally, a time of delivery of the medicament. The software may be provided in the form of a software application, or "app", that may be downloaded from a library or store over the Internet.

[0034] An example method according to an embodiment of the invention will now be described with reference to Figures 3 to 9.

[0035] Starting at Figure 3, step 3.0, the video camera 21 is controlled to begin recording images of at least part of the injection device 1 (step s3.1), including the dosage window 13. In some embodiments, the app is configured to cause the processing arrangement 22 to provide guidance to the user while the video is being recorded, by providing instructions regarding positioning of the injection device 1 relative to the camera 21 based on a "live view" of the field of view of the camera 21. For example, the app may be configured to guide the user to position the camera 21 at a distance at which the camera 21 can obtain a good focus on the dosage window 13. In certain embodiments, such focus may be achieved when the distance between the camera and the injection device 1 is approximately 30 cm.

[0036] Further, if medicament information is included only in another part of the injection device 1, such as the label 19, then the app may cause the processing arrangement 22 to instruct a user of the data collection device 20, 33 to include that part of the injection device 1 by providing a message on the display 29 and/or an announcement over the speaker 30.

[0037] In this embodiment, the processing arrangement 22 then performs pre-processing (step s3.2), to assess and, if required, improve video data quality by executing the following steps:

- Defective and bad pixel correction
- Light correction
- Distortion
- Jitter

[0038] For example, an exposure control algorithm may adjust the operation of the video camera 21 to correct for images that are too bright or too dark by controlling exposure parameters for the video camera 21 and/or controlling additional lighting, where provided, for example, in an embodiment where the data collection device 20 includes a flash unit (not

shown). It is noted that the pre-processing is an optional feature. The app may be designed to perform to the required standard without pre-processing of the image.

[0039] The distance between the injection device 1 and the video camera 21 is not fixed and the orientation of the dosage window 13 and, where provided, the label 19, relative to the camera 21 may also vary. In view of this, the processing arrangement 22 adjusts the scale of images within the video recording so that the size of the characters displayed within the dosage window 13 are within a predetermined range (step s3.3).

[0040] The processing arrangement 22 may further adjust the images within the video recording by correcting skew of the characters displayed in the dosage window 13 based on the orientation of the injection device 1 relative to the camera and/or any slanting of the characters displayed in the dosage window 13 (step s3.4). For instance, the numbers in the dosage window 13 might be slanted for ease of recognition and positioning by a user, but may be easier to decode by the data collection device 20 if the slant is removed.

[0041] The scale and skew adjustments may be based on an analysis of features of the injection device 1 of predetermined shape and/or size. For example, the processing arrangement 22 may identify the dosage window 13, label 19, a logo (not shown) on the injection device 1 and/or other features of the injection device 1 in the image and, based on information regarding the expected shape and/or size of those features, adjust the scale and alignment of the images taken by the video camera 21 and correct for skew of text and numbers included in the images.

[0042] In some embodiments, the app may also control the processing arrangement 22 to determine whether the dosage window 13 and a particular part of the injection device 1, such as the label 19, that includes medicament information are included in the video images (step s3.5). The determination may be based on the scale of the injection device 1 in the image and the location of one or more parts of the injection device 1 within the image. The app may optionally provide guidance to the user to adjust the positioning of the injection device 1 relative to the video camera 21 so that the relevant parts of the injection device 1 are within a field of view of the video camera 21.

[0043] The processing arrangement 22 then attempts to recognise characters from at least one image of the dosage window from the video recording, using Optical Character Recognition (OCR) software included in the app (step s3.6), in order to determine a number or other dosage indication displayed in the dosage window 13 (step s3.7).

[0044] Figures 4 and 5 depict a portion of the dosage window 13, showing examples of digits that may be displayed. In Figure 4, a dosage has been dialled into the injection device 1 such that the a digit 34, in this case the number 6 indicating 6 IU, is displayed centrally in the dose window 13. In Figure 5, a dosage of of 7 IU has been dialled into the injection device 1 such that digits 35, 36, representing the numbers 6 and 8 respectively, are both displayed in the dose window 13 and the space between these numbers occupies the central region of the

dose window 13. In this particular embodiment, the processing arrangement 22 is configured to execute an algorithm allowing both of the situations depicted in Figures 4 and 5 to be decoded accurately.

[0045] The OCR process comprises the steps of:

- Binarization
- Segmentation
- Pattern matching
- Position calculation

[0046] Due to the high reliability requirements of the sensor device 2, there may in some embodiments be two OCR algorithms that are operated in parallel. The two OCR algorithms have the same input (image) and are intended to provide the same output. They both perform similar steps however the individual methods used in each step may vary. These two OCR algorithms may differ in one of the binarization, segmentation, pattern matching and position calculation steps or in more than one of these steps. Having two OCR-parts which use different methods to provide the same result increases the reliability of the entire algorithm as the data has been processed in two independent ways.

[0047] In the OCR process, the colour or greyscale image obtained from the video camera 21 and adjusted as described above is converted into a purely black and white image 37, such as that depicted in Figure 6, through a binarization process. In an example where dark numbers are presented on a bright background in the dosage window, the black and white image would indicate the presence of digits 38, 39 with black pixels and the absence of digits with white pixels, as shown in the example of Figure 6. In some embodiments a fixed threshold is used to separate between black and white pixels. Pixels that have a value at or above the threshold become white, pixels below the threshold become black in the binarized picture. A high threshold will lead to artefacts (black parts in white areas), whereas a low threshold has the risk that in some cases parts of digits are missing. In some embodiments, the threshold is chosen so that in no case are parts of digits are missing because the algorithm is in general robust against artefacts (i.e. an accurate OCR process can be performed in the presence of some artefacts). In tests where an image was analysed using 256 grey values, a threshold value of 127 showed good results.

[0048] The use of a fixed threshold is possible where light correction has been performed, for example, in the pre-processing. The combination of the light correction and the fixed threshold is similar to a windowed mean binarization. A windowed mean binarization compares the pixel-value with the mean value of the pixels of the area where it is located. Performing the light correction step before the distortion and slant correction steps means that more information is available to be used for the OCR process, which has been shown to yield better results on the edges and corners of the picture.

[0049] Alternatively, the Otsu threshold method may be applied to the captured greyscale image to produce a binary image similar to the binarized image 37 shown in Figure 6. In some alternative embodiments, the binarization may be omitted and the OCR part of the algorithm may be performed on the captured colour or greyscale image.

[0050] Segmentation is then performed. The goal of this part of the algorithm is to determine the exact location of each visible or partly visible number in the image. To achieve this, the algorithm defines the boundaries of the visible digits by finding the edges of the digits. This is generally accomplished in two steps, which may be performed in any order. Referring again to Figures 4 and 5, the processing arrangement 22 may perform a "vertical projection" in which the pixel columns making up the binarized image 37 are analysed. Each pixel column is analysed individually and the sum of the number of black pixels in each column is computed. In some embodiments, only a pixel column having zero black pixels defines the edge of a number. Alternatively, a low threshold for the number of black pixels may be set to account for dirt, scratches and other disturbances. Difference values for adjacent columns are calculated and the boundary having the greatest difference represents the edge of the number. Additionally, the pixel content of overlapping groups of columns (e.g. three adjacent columns) may be calculated to aid in determining the horizontal edges of the numbers.

[0051] The processing arrangement then performs a "horizontal projection" in which the pixel rows making up the binarized image 37 are analysed. This proceeds in a similar manner to that as described above with regard to the vertical projection.

[0052] The expected result of the horizontal projection is added to that of the vertical projection such that the edges of the visible numbers are identified. The processing arrangement 22 may be pre-programmed with the expected height (in pixel rows) of a full number, and so is able to recognise the presence of partially visible numbers.

[0053] In another embodiment, the "horizontal projection" and the "vertical projection" may be based on an analysis where the sum of white pixels is computed, provided that the expected number of white pixels in each row and column is known.

[0054] Knowing the exact location allows for using only the part of the image which represents the visible number or numbers for the next steps in the OCR process. By this any impact of other objects besides the number, e.g. dirt, scratches and other disturbances, can be reduced. Further, the total number of pixels to be processed in subsequent steps, e.g. in the pattern matching step, is also reduced. This helps reducing resource requirements. This also helps increasing performance. In addition, knowing the exact location also supports determining the vertical position relative to the centre of the image.

[0055] The next step in the OCR process is to select one of the visible numbers to be decoded and identified. This is done by designating one of the numbers as the "primary digit row". The primary digit row is selected based on which visible number has the greatest height. This is because all of the numbers printed on the sleeve 70 have approximately the same height and

it can be assumed that the number having the greatest height will be fully visible and therefore easy to decode with a high degree of certainty. In the example shown in Figure 7, the number "6" has a greater height than the partially visible numbers above and below and so is selected as the primary digit row. In the example shown in Figure 8, both the numbers "6" and "8" are fully visible and have the same height. In this case, the uppermost number is selected as the primary digit row. The primary digit row is the number which is subsequently used to determine the dose dialled into the injection device 1.

[0056] A standard injection device 1 for self administration of insulin can inject any number of units of medicament from 1 to 80 IU. Therefore, in order to properly decode the number identified as the primary digit row, it must be determined whether the number consists of one or two digits. The processing arrangement 22 therefore performs a series of steps in order to determine whether each number consists of one or two digits, and in the latter case, to separate the digits from each other. The processing arrangement 22 may use the column pixel information previously calculated for this purpose. In the example shown in Figure 9, 9 IU of medicament have been dialled into the injection device 1. The expected results of the horizontal and vertical projections are shown. The number "10" is of greater height than the number "8" and is therefore selected as the primary digit row.

[0057] After this the processing arrangement 22 determines whether the selected primary digit row is wider than a pre-defined "maximum digit width" value. The processing arrangement 22 may be pre-programmed with information relating to the expected size of the numbers in the captured images, so that a maximum expected width for a single digit can be defined. In order to increase reliability, the maximum width may be set as a small number of pixel columns more than the widest number. If the width of the primary digit row is the maximum digit width or less, it is assumed that the row contains a single digit. If the primary digit row is too wide to be a single digit, then a second vertical projection is then performed on the primary digit row (rather than on the whole image). In addition, the expected width of each individual digit may be used to predict the point at which the separation should occur.

[0058] The exemplary field of view 900 shown in Figure 9 is a diagrammatic representation in which the numbers are well spaced. In other arrangements, the numbers may be displayed quite close together in the dosage window, owing to limited available space and the need for the numbers to be readable to a user. Thus, after binarization, the two digits making up the number may not be cleanly separated, i.e. there may not be a column having no black pixels between the two digits. This is the case in the exemplary binarized image shown in Figure 6, in which the "7" and "4" of the upper digits 37 do not have a pixel column between them containing no black pixels. In this case, the expected width of each individual digit is again used to predict the point at which the separation should occur. If the predicted column contains black pixels, then the deviations of this column from adjacent columns are calculated to determine the best separation point. In this situation, as it is not clear whether the black pixels in the chosen separating column belong to the left or right digit, they are ignored. This has been shown to have a minimal effect on the reliability of the OCR process to correctly identify the digits.

[0059] A pattern matching process is then performed to identify the digits in the primary digit row. Templates for each number may be pre-programmed via the app and the identified digits may then be compared to these templates. In a straight forward approach the pattern matching could be performed on a pixel-by-pixel basis. However, this may require high computing power and may be prone to position variation between the image and the template. Where templates are used, the app may be configured to cause the processing arrangement 22 to perform other types of manipulation on the images numbers, for example by changing the size of one or more digits, cropping the numbers to a defined pixel area and shearing numbers printed in a italic font into an upright position. These manipulations may be performed before a pattern matching comparison with the stored templates. Alternatively, these manipulations may be performed in preprocessing before the binarization process. Additional shading, distortion and exposure correction may also be performed.

[0060] In some other embodiments, a feature recognition process is performed. Features may be horizontal, vertical or diagonal lines, curves, circles or closed loops etc. Such features may be recognized in the image of the selected number and compared with templates.

[0061] In yet further embodiments, the pattern matching algorithm may be based on a vector comparison process. For example, the templates may be in the form of vectors describing the position and length of each line (continuous run) of black pixels. In one example, the position and length relate to the absolute position in the respective line. In another example, the position and length relate to a vertical line extending through the centre of the template. The captured binary image of each digit may similarly be converted into vectors and compared with each stored template in turn to find the best match. When comparing the vectors of the captured image with a particular digit template, any deviations result in a penalty being applied for the likelihood of a match between the image and that template. The magnitude of the penalty may depend on the number of missing or extra black pixels in the image compared to the template. After the digit image has been compared with each template and all of the penalties have been applied a decision is made as to which digit is present. In good optical conditions, the correct template will have a very low penalty, while all other templates will have a high penalty. If the primary digit row consists of two digits, this process is performed on both digits and the processing arrangement 22 can then combine the outcomes to produce a final result for the number.

[0062] Special measures may exist for certain digits. For example, "1" deviates substantially in width from all other digits resulting in common misdetections. To counter this, if a binary image of a digit is wider than the expected width of "1", then it receives an additional detection penalty when being compared with the stored vector template of "1".

[0063] In some exceptional cases, if the confidence level in the result of the pattern matching of the primary digit row is below a certain threshold (e.g. 99%), then the processor may perform a second pattern matching process on one or more of the other visible or partially visible numbers. Since the order of the numbers is known, this second pattern matching can

act as a check that the first pattern matching returned the correct result.

[0064] If the confidence level in the result is still not high enough, then steps s3.1 to s3.6 may be repeated for a second image from the video recorded by the video camera 21. Alternatively, an error message may be displayed and, optionally, an instruction issued to the user through the output arrangement 29, 30 to continue capturing video images of the dosage window 13 or to enter dosage information manually, via the input arrangement 27, 28.

[0065] If the digit or digits of the primary digit row have been successfully identified, a weighting function is applied in order to determine a dose displayed in the dosage window 13 (step s3.7). To formulate the weighting function, the vertical position of the primary digit row relative to the centre of the dosage window 13 may be determined. This may be done by calculating the offset of the middle pixel row comprising the primary digit row relative to a pixel row representing a centre line of the dosage window 13 in the image.

[0066] For example, in some embodiments the optical sensor comprises a rectangular 64 x 48 array of photosensitive elements. The resulting binary image is a pixel array having these same dimensions. The 24th and/or 25th pixel row may be designated as the central row of the image. The position of the middle pixel row comprising the primary digit row is determined. The offset, in pixel rows, between the middle pixel row comprising the primary digit row and the central row or rows of the image is then calculated. This offset may be positive or negative depending on the direction of the offset. The offset is converted into a fraction by dividing it by the distance (in pixel rows) between successive numbers before being applied to the determined numbers accordingly. The offset therefore allows for determining the rotational position of the number relative to the sensor. If the central pixel row of the primary digit row is the same as the central pixel row of the image, then the offset is zero and the position is equal to the primary digit row number. However, there is likely to be some offset in most circumstances.

[0067] The distance between successive numbers printed on the number sleeve 70 is constant, since the numbers represent a dose which is related to a discrete mechanical movement of the injection device mechanism. Therefore, the distance (in pixel rows) between successive numbers in the captured image should also be constant. The expected height of the numbers and spaces between the numbers may be pre-programmed into the app. As an example, the expected height of each numbers may be 22 pixels and the expected height of the spaces between the numbers may be 6 pixels. Therefore, the distance between the central pixel rows of successive numbers would be 28 pixels.

[0068] Continuing this example, if the pixel rows are numbered sequentially from the top to the bottom of the image, the application of the weighting function may be defined mathematically as:

Position = primary digit row number + $[2 \times \text{offset} / (\text{expected height of number} + \text{expected height of space})]$

Where offset = image row number corresponding to the centre of the dosage window – primary digit row central row number

[0069] Thus, if the primary digit row is in the upper half of the image, then the offset is positive and if the primary digit row is in the lower half of the image, then the offset is negative. For example, if the number shown in the primary digit row is "6" and the offset is zero, then the calculated position would be:

$$\text{Position} = 6 + [2 \times 0 / (28)] = 6$$

[0070] Thus a result of "6" would be returned as expected.

[0071] In another example, where 75 IU are dialled into the injection device 1, if the top number, "74", is selected as the primary digit row and there is a positive offset of 11 pixel rows according to the equation above, and again assuming a combined number/space height of 28 pixels, the calculated position would be:

$$\text{Position} = 74 + [2 \times 11 / (28)] = 74.79$$

[0072] This result is then rounded up to the nearest whole number, to give a position determination of "75" as expected.

[0073] The skilled person will appreciate that the above described weighting function and position determination represents only one example and that numerous other calculation methods may be used to arrive at the same result. The skilled person would also appreciate that the above described mathematical calculation may be modified and improved to reduce the computation time. Thus the exact form of the weighting function is not essential to a definition of the present invention.

[0074] In some injection devices, due to space restrictions and the need for the numbers to be of a certain size, only even numbers are presented in the dosage window 13. In some other injection devices, only odd numbers may be displayed. However, any number of units of medicament can be dialled into the injection device 1. In other injection devices, both even and odd numbers may be presented and it may be possible to dial half-unit doses into the injection device. The injection device may be limited to a maximum dialled dose of 80 IU. Alternatively, only every 3rd, 4th or 5th number may be displayed and doses between the numbers may be indicated by tick marks. In view of this, the app may include instructions for controlling the processing arrangement 22 to identify the numbering sequence used in the injection device 1. For example, the user may be prompted to enter information regarding the injection device 1 via a keypad 27 or touch-screen 33 or information obtained from the image, for example from the text or a barcode on the label 19 may be used. The app may include a look-up table or other information indicating the numbering sequences used for various injection devices 1. The processing arrangement 22 may then determine the selected dose based on both OCR data

and the appropriate numbering sequence for the injection device 1. Alternatively, or additionally, a modified form of the weighting function may be used, as the height of the numbers and size of the space between the numbers may also be modified.

[0075] The method may optionally include post-processing, such as performing sanity checks and hysteresis calculations. Alternatively, the result of the OCR process may be finalised without post-processing.

[0076] The OCR process, as described above in steps s3.6 to s3.7, is then repeated on at least one subsequent image from the video, in order to determine whether the dialled dosage has changed (step s3.8). This step is intended to determine whether the dosage identified in step s3.7 represents a dosage to be delivered by the injection device 1 or whether the user has continued to adjust the dialled dosage using the knob 12. In some embodiments, the processing arrangement 22 is configured to identify the last determined dosage in the video to be the actual dosage delivered to the user. In other example embodiments, the processing arrangement 22 may identify an actual dosage delivered by the injection device 1 based on the detection of the same dialled dosage in a predetermined number of successive, or a sequence of substantially successive, video frames in steps s3.6 to s3.7.

[0077] Information regarding the type of medicament may be obtained by one or more of using OCR from a part of the image including the label 19, extracting and interpreting a barcode from a part of the image including the label 19 or by identifying a colour of a part of the injection device 1 that indicates the medicament type from the image (step s3.9).

[0078] In embodiments where colour detection is used, the numbered sleeve 70 of the injection device 1 may be configured to provide reference colour information to allow one or more colours in the image to be identified correctly. For example, the background of the printed numbers may be used to provide a white balance level for calibrating the colours of the components of the injection device 1 as shown in the image.

[0079] Information regarding the time at which the medicament was delivered by the injection device 1 is obtained from timestamp data associated with the video recording (step s3.10).

[0080] The information obtained from the video may then be stored in the random access memory 24 of the data collection device 20 (step s3.11) and/or transmitted to another device via a network, such as a cellphone network, personal area network, WLAN or the Internet, using the communications equipment 25, 26 (step 3.12). On this manner, the administration of medicament to a patient may be recorded and/or monitored. The process ends at step s3.13.

[0081] Another embodiment of a method that may be used to collect from the injection device 1 using the data collection device is shown in Figure 10.

[0082] Starting at step 10.0, steps 10.1 to 10.10 correspond to steps 3.1 to 3.10 respectively.

[0083] The method shown in Figure 10 includes additional steps of analysing the video recording to determine whether the injection device 1 is activated to deliver more than one dosage of medicament. As noted above, the injection device 1 may have an upper limit to the amount of medicament that may be delivered in one injection, such as 80 IU. In practice, more than one actual injection may be needed in order for a user to receive their required dose of medicament. If the user requires a dose above a maximum dosage of the injection device 1, for instance, above 80 IU in the example noted above, two injections might be administered in quick succession.

Alternatively, or additionally, the video may include images of a user performing one or more "prime shots" to eliminate air from the injector pen that should be disregarded when determining the dosage delivered to the user.

[0084] At step s10.11, the processing arrangement 22 determines whether the video captured by the video camera 21 includes images of a further dosage being dialled into the injector pen 1 by repeating the OCR process described in relation to steps s10.6 and s10.7 of on one or more subsequent images from the video. For example, when the SoloSTAR® pen, mentioned above, is used to administer an injection, the number displayed in the dosage window 13 decreases to zero as the medicament is delivered. Therefore, a sequence of images in the video showing a changing number in the dosage window 13 after a dialled dosage has been identified in step s10.7, or the subsequent detection of a non-zero character in the dosage window 13, may be considered an indication that a further delivery of medicament is being performed by the user.

[0085] If a further delivery of medicament is indicated, the processing arrangement 22 then determines whether the previous delivery of medicament corresponded to a "prime shot" or an actual injection of medicament (step s10.12). A "prime shot" may be detected based on the determined dosage. For example, the detection of a dialed dosage of 2 IU or less in step s10.8 or s10.9 may be considered to correspond to a "prime shot", rather than an injection received by the user. Alternatively, or additionally, the time stamp obtained at step s10.10 and a time stamp associated with the image on which the detection of a new dosage being dialled into the injection device 1 is based in step s10.11, or the time between detections of further dosages in step s10.11, may be used to indicate whether a "prime shot" has been performed. The administration of an injection into a user may require the needle to remain in the user's body for several seconds, for example, 10 seconds in certain insulin injections. Furthermore, where a second injection is to be performed, the user would be expected to change the needle 15 after the first injection, increasing the time interval between detections of dialled dosages by the OCR process in steps s10.6 to s10.7 and step s10.11. Where that time interval exceeds a predetermined limit, such as 10 seconds, a second injection may be indicated. If the time interval is less than the predetermined limit, then the processing arrangement 22 may determine that the previous activation of the injection device 1 was a "prime shot".

[0086] In embodiments where the OCR process is performed while the video is being captured by the video camera 21, the data collection device 20 may output a request to the user to indicate whether a second injection is being made and/or whether a "prime shot" has been

performed, via the display 29 and/or the speaker 30. The user may respond to the request via the input arrangement 27, 28, 31.

[0087] If it is determined that only one injection was delivered at step s10.11, then the overall dosage received by the user is determined to correspond with the dosage detected in step s10.7.

[0088] If it is determined that a second injection has been delivered (step s10.11) and that neither injection was a 'prime shot', then the dosages is determined in steps 10.7 and 10.11 are added together to determine an overall dosage received by the user (step s10.13). However, if it is determined that one or more dosages detected in steps s10.7 and 10.11 related to a "prime shot" (step s10.12), then the respective determined dosages is not included in the overall determined dosage (step s10.14) and a check for further injections is made (step s10.11).

[0089] In an alternative embodiment, steps 10.12 to s10.14 may be omitted and, where further dosages are detected (step s10.11), data relating to detected dosage may be stored and/or transmitted for later analysis.

[0090] Information regarding the type of medicament and time stamp information may be stored and/or transmitted (steps s10.15, 10.16) as described above in relation to steps 3.11 to 3.12 of Figure 3. The process then ends (step s10.17).

[0091] As shown by the embodiments discussed above, the provision of an app or similar software product to obtain information regarding an injection, other medical treatment or the operation of other equipment may permit more accurate and/or reliable recording of such information using a device, such as a wearable electronic device, that is commonly available and familiar to the user. Since the embodiments described above do not require the manufacture and distribution of a specialised data collection device, they may, potentially, reduce the costs and complexity of providing recordal and/or monitoring of treatment or operations.

[0092] In the embodiments described above, video is captured, processed and analyzed by one data collection device 20. However, in other embodiments, the data collection device 20 may be configured to capture the video using its camera 21 and then transmit the captured video to a computer via a network, such as a wireless local area network, a personal area network, a cellular communication network or the Internet, where the computer includes a processing arrangement configured to process and analyse the video to determine a dosage displayed in the dosage window 13.

[0093] While the embodiments above have been described in relation to collecting data from an insulin injector pen, it is noted that embodiments of the invention may be used for other purposes, such as monitoring of injections of other medicaments or other medical processes.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- [US2013197445A \[0004\]](#)
- [WO2013120774A \[0004\]](#)
- [WO2013045506A \[0004\]](#)
- [US2011295215A \[0004\]](#)
- [US2011118700A \[0004\]](#)
- [US2014005950A \[0004\]](#)
- [US2003076408A \[0004\]](#)

Patentkrav

1. Fremgangsmåde til registrering af en medikamentdosis ved anvendelse af en bærbar elektronisk dataindsamlingsanordning (20), som omfatter:

optagelse ved hjælp af et videokamera (21) i dataindsamlingsanordningen (20) af en video, der viser en medikamentdosisindikator i en medikamentadministrationsanordning (1);

justering af en skala for et billede i videoen afhængig af afstanden mellem medikamentadministrationsanordningen (1) og videokameraet (21);

justering af billedet for skævhed af en eller flere karakterer, der vises på en komponent (13) af medikamentadministrationsanordningen i videoen;

bestemmelse af positionen af mindst én af den ene eller de flere karakterer i billedet;

identificering af den mindst ene karakter ved anvendelse af optisk karaktergenkendelse; og

bestemmelse af en medikamentdosis, der indikeres af medikamentdosisindikatoren, baseret på et resultat af den optiske karaktergenkendelse.

2. Fremgangsmåde ifølge krav 1, som omfatter bestemmelse af, om mere end én administration af medikament er registreret i videoen.

3. Fremgangsmåde ifølge krav 2, der som reaktion på en bestemmelse af, at mere end én administration af medikament er registreret i videoen, omfatter bestemmelse af mindst en anden medikamentdosis baseret på mindst én karakter, der identificeres ved anvendelse af optisk karaktergenkendelse på mindst et andet billede af medikamentdosisindikatoren i videoen, og bestemmelse af en samlet medikamentdosis, der er modtaget af en bruger, baseret på den bestemte medikamentdosis og den betemte anden medikamentdosis.

4. Fremgangsmåde ifølge krav 2 eller 3, der som reaktion på

en bestemmelse af, at mere end én administration af medikament er registreret i videoen, omfatter bestemmelse af, om den mere end ene administration af medikament indbefatter et eller flere forfyldningsskud.

5

5. Fremgangsmåde ifølge et hvilket som helst af ovennævnte krav, som omfatter opnåelse af farveinformation fra billedet og identificering af en type af medikament, der skal dispenseres, baseret på farveinformationen.

10

6. Fremgangsmåde ifølge et hvilket som helst af ovennævnte krav, hvor medikamentadministrationsanordningen er en injektorpen, der omfatter en bevægelig komponent til valg af mængden af medikament, der skal dispenseres.

15

7. Computerprogram, der omfatter computerlæsbare instruktioner, der, når de effektueres af en processor, forårsager udførelse af en fremgangsmåde ifølge et hvilket som helst af ovennævnte krav.

20

8. Applikation til en bærbar elektronisk anordning, hvor applikationen omfatter et computerprogram ifølge krav 7.

9. System, der omfatter en medikamentadministrationsanordning (1) og et dataindsamlingsapparat til registrering af en medikamentdosis, hvilket dataindsamlingsapparat omfatter:
en bærbar elektronisk anordning, der indbefatter et videokamera (21); og

30 en behandlingsindretning (22), der er konfigureret til at:
optage en video ved anvendelse af videokameraet (21), hvilken video indbefatter mindst ét billede af en medikamentdosisindikator på en medikamentadministrationsanordning;

35 justere en skala for billedet afhængig af afstanden mellem medikamentadministrationsanordningen (1) og videokameraet (21);

justere billedet for skævhed af en eller flere karakterer, der

vises på en komponent (13) af
medikamentadministrationsanordningen (1);

bestemme positionen af mindst én af den ene eller de flere
karakterer i billedet;

5 identificere den mindst ene karakter ved anvendelse af optisk
karaktergenkendelse; og

bestemme en dosis, der indikeres af
medikamentdosisindikatoren, baseret på et resultat af den
optiske karaktergenkendelse.

10

10. System ifølge krav 9, hvor den bærbare elektroniske
anordning er konfigureret til at blive båret på hovedet af en
bruger.

15 11. System ifølge krav 9 eller 10, hvor
behandlingsindretningen er konfigureret til at bestemme, om
mere end én administration af medikament er registreret i
videoen.

20 12. System ifølge krav 11, hvor behandlingsindretningen er
konfigureret til at reagere på en bestemmelse af, at mere end
én administration af medikament er registreret i videoen, ved
hjælp af bestemmelse af mindst en anden medikamentdosis
baseret på mindst én karakter, der identificeres ved
25 anvendelse af optisk karaktergenkendelse, på mindst et andet
billede af medikamentdosisindikatoren i videoen og bestemmelse
af en samlet dosis, der er modtaget af en bruger, baseret på
den betemte medikamentdosis og den betemte anden
medikamentdosis.

30

13. System ifølge krav 11 eller 12, hvor
behandlingsindretningen er konfigureret til at reagere på en
bestemmelse af, at mere end én administration af medikament er
registreret i videoen, ved hjælp af bestemmelse af, om den
35 mere end ene administration af medikament indbefatter en eller
flere forfyldningsskud.

DRAWINGS

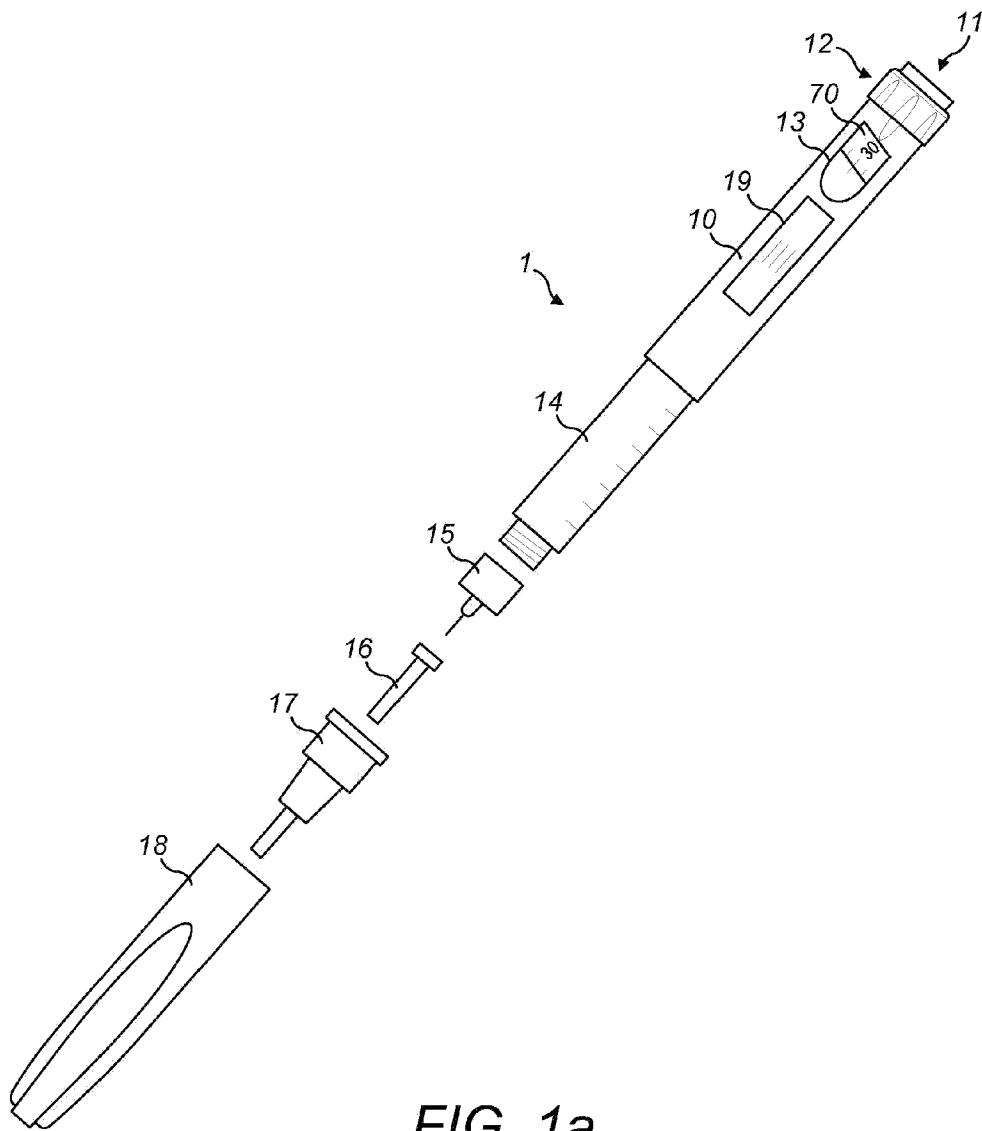


FIG. 1a

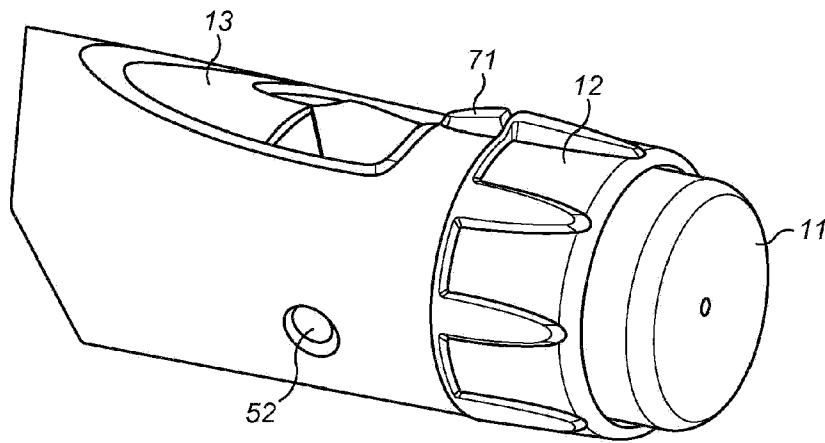


FIG. 1b

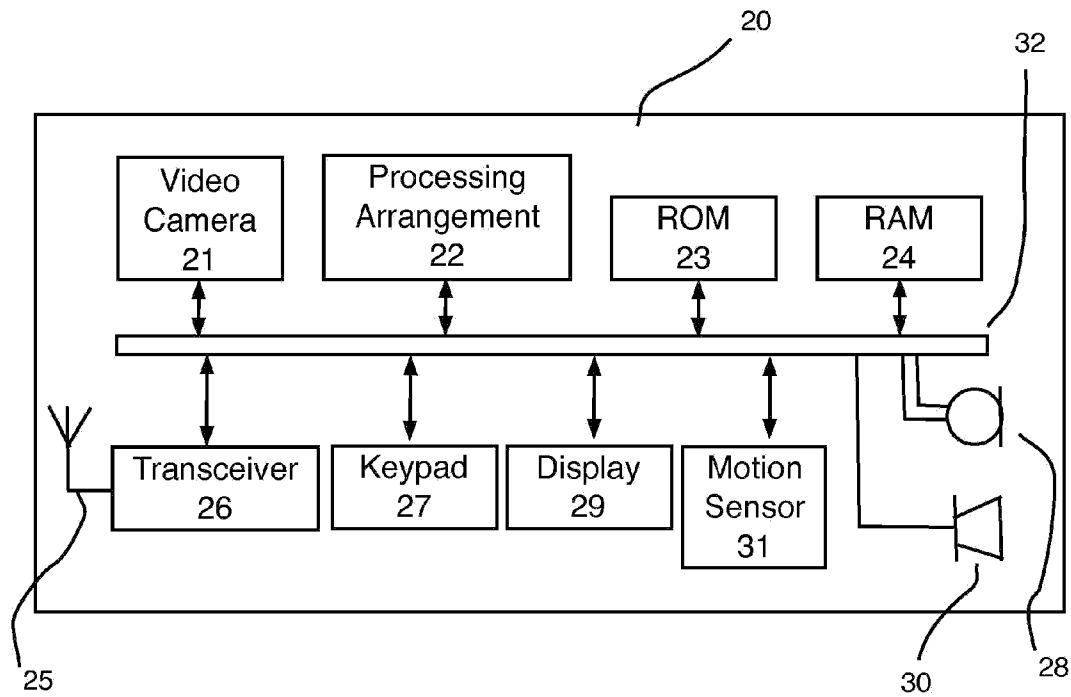


Figure 2

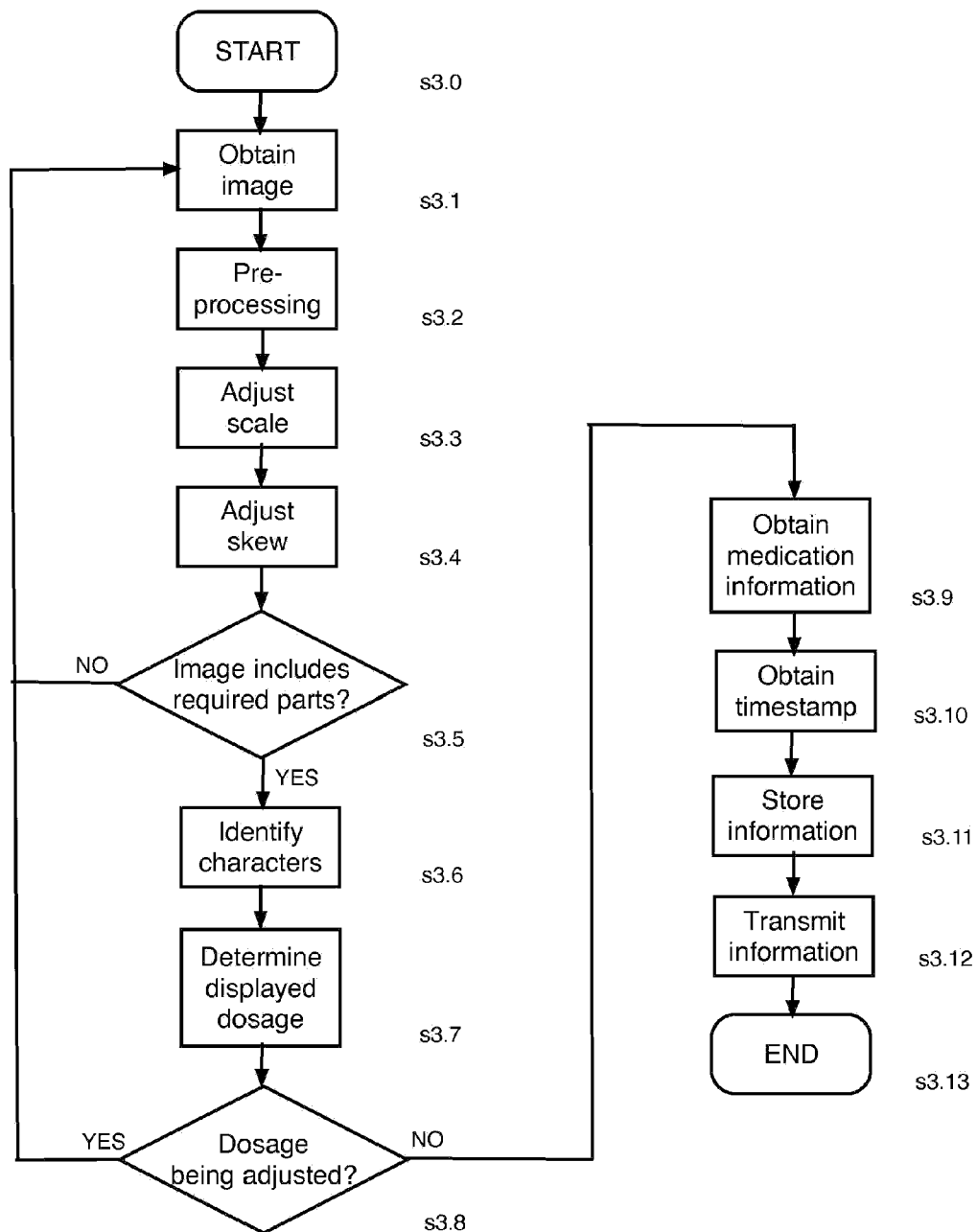


Figure 3

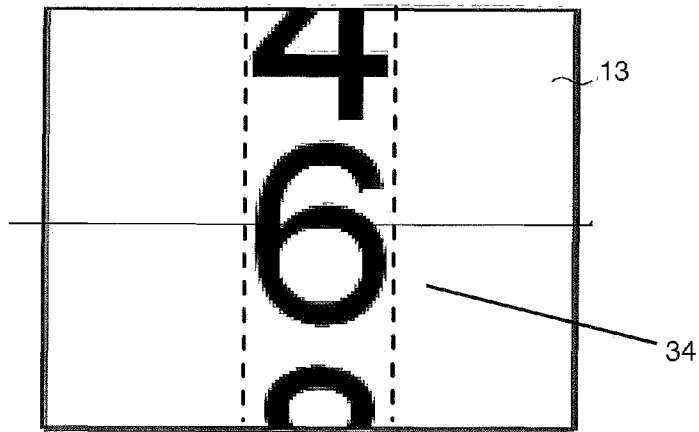


FIG. 4

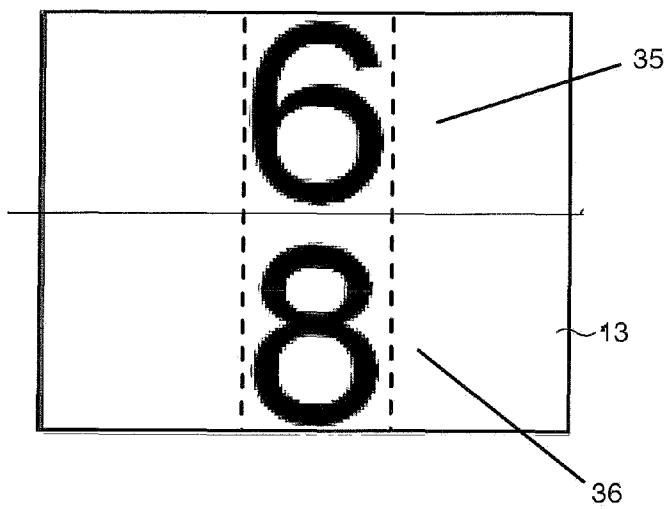


FIG. 5

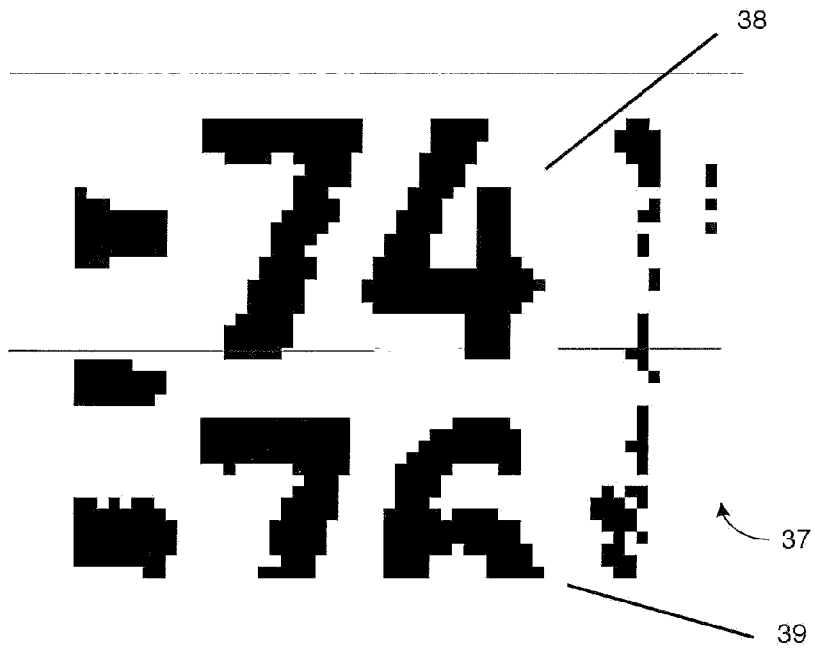


FIG. 6

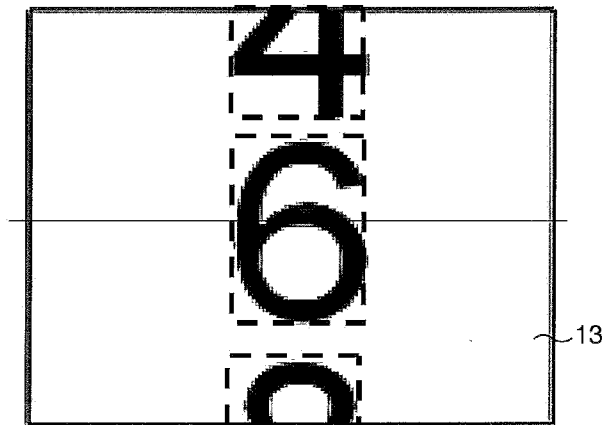


FIG. 7

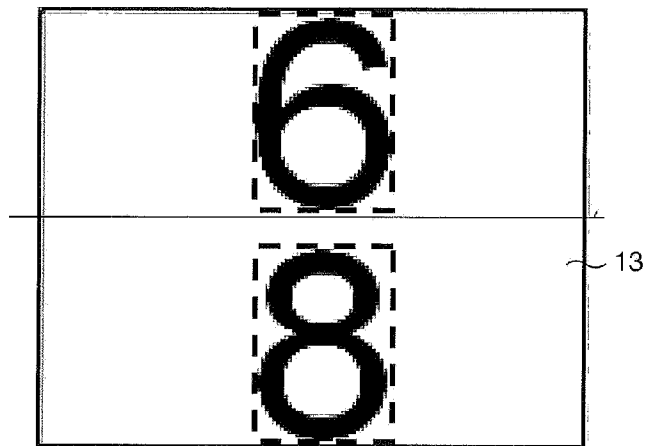


FIG. 8

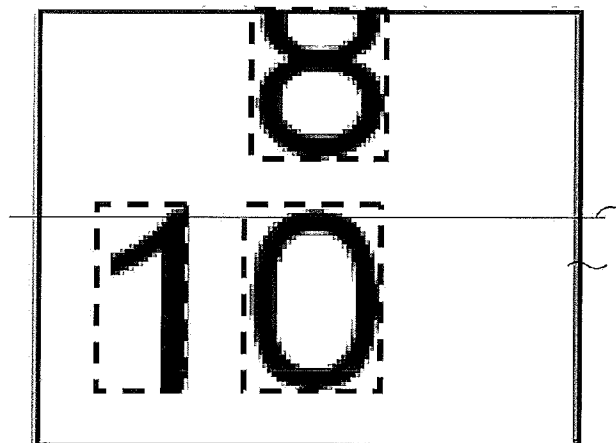


FIG. 9

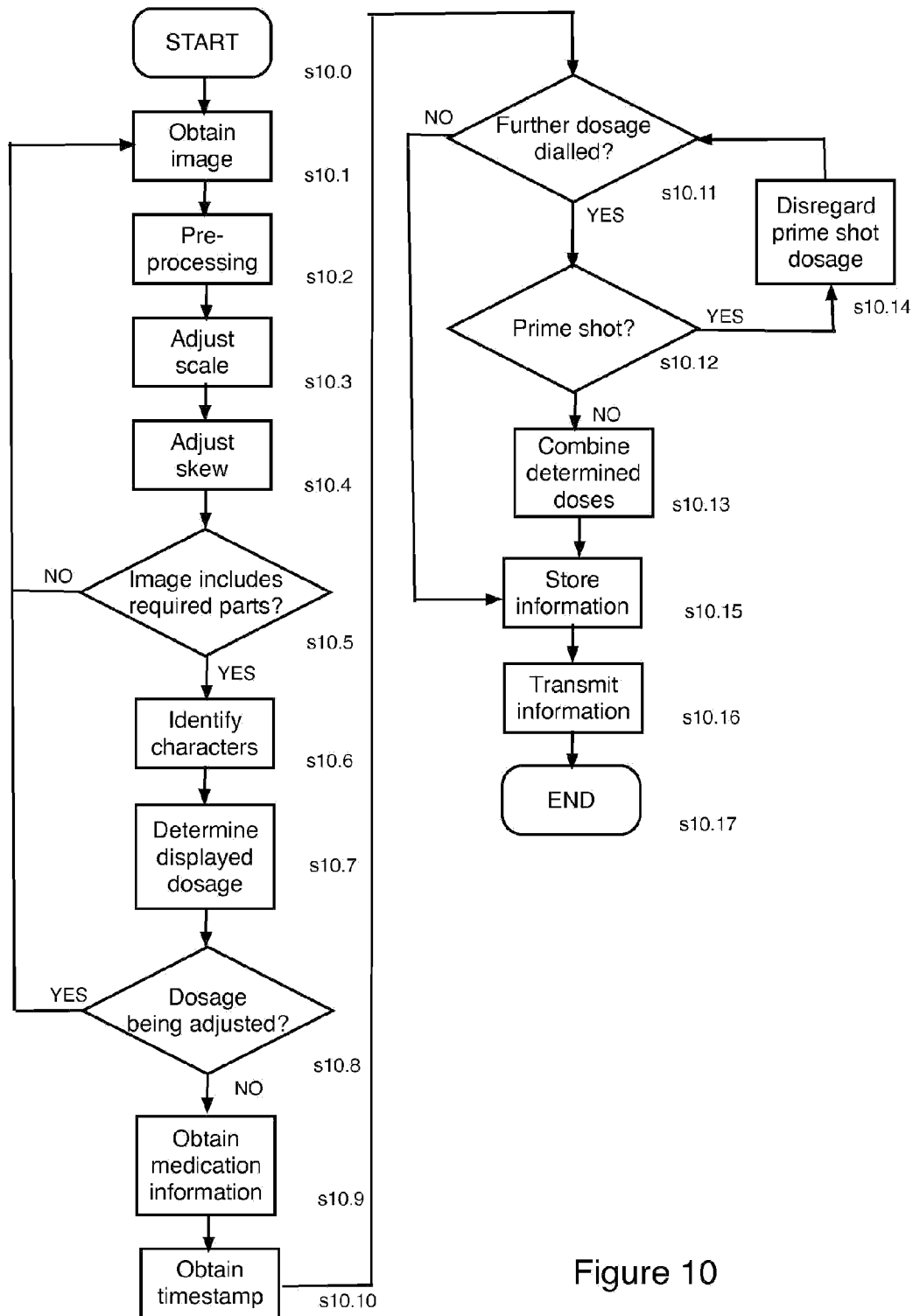


Figure 10