



(51) International Patent Classification:

G06K 7/00 (2006.01) G06K 7/10 (2006.01)
G06K 17/00 (2006.01)

(21) International Application Number:

PCT/EP2020/058424

(22) International Filing Date:

25 March 2020 (25.03.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

19382240.0 02 April 2019 (02.04.2019) EP

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(54) Title: METHOD, SYSTEM AND DEVICE FOR MONITORING AND LABELLING BIOLOGICAL AND PHARMACEUTICAL PRODUCTS

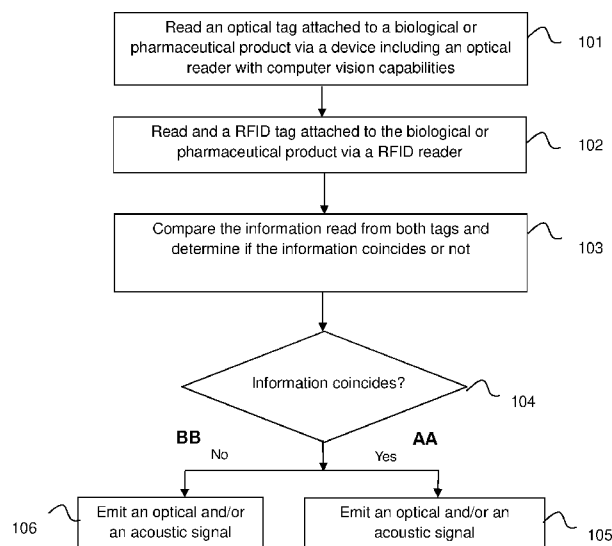


Fig. 1

(57) Abstract: A method, a system and a device for monitoring and labelling biological and pharmaceutical products are provided. The method comprises reading an optical tag attached to a biological or pharmaceutical product via a device including an optical reader with computer vision capabilities and a RFID tag via a RFID reader. A comparison of the information read is performed by a processor, the latter further determining if the information of both tags coincides or not, emitting a first indication signal if the information coincides or a second indication signal if the information does not coincide. The processor can determine whether additional information included in the optical tag has to be added to the RFID tag.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

**METHOD, SYSTEM AND DEVICE FOR MONITORING AND LABELLING BIOLOGICAL
AND PHARMACEUTICAL PRODUCTS**

Technical field

- 5 The invention generally relates to management and label systems and methods. In particular, the invention relates to a method, system and device for monitoring and labelling biological and pharmaceutical products.

Background of the Invention

- 10 Biological materials, medicines and pharmaceutical products used in healthcare require to be clearly identified and traceable from their origin (manufacturer or biological donor) until their final destination or use, in order to avoid medical or health hazards due to incompatibility of a patient with certain drugs or a biological specimen from a donor, as well as to be able to trace a product if a problem has been detected or else it has been mislaid.

- 15 That usually implies that every element must be controlled univocally, so it is usually enclosed in plastic bags, bottles or other many kinds of containers depending on its physical properties, nature and storage needs. To identify univocally every element, an identification label is usually linked to it.

- 20 The industry uses labels that can combine descriptive and detailed text or data mixed with one or more barcodes (or other data matrix) as identifiers and/or descriptors. The barcodes can be read one by one with electronic readers that need to be placed very close to the label.

However, the process of reading said labels is not always reliable and/or efficient in certain situations, such as: when the label is wet or frozen, when the label has deteriorated or when the label has been mislaid, which means that the biological or pharmaceutical product cannot be properly identified until a manual action or corrective measure has been performed.

- 25 In order to avoid said issues, the use of Radio-frequency identification (RFID) tags has increased substantially. RFID tags are electronic sensors with an identification number that can store additional information in its internal memory. Furthermore, RFID tags can be read at a variable distance using wireless radio frequency communication networks, which means that reading one or more RFID tags can be done without manual handling, and therefore

they are increasingly used to increase productivity in manufacturing and distribution industries.

In general, the RFID tag is placed redundantly with a physical readable data matrix label, such as a barcode, wherein both elements store, at least, part of the same information, so that a product can still be monitored and/or traced in the event of one of the labels being damaged.

There are known some patents and patent application in the field.

For example, US 7158030-B2 discloses a medication tracking and/or medical assistance device and method comprising an RFID tag coder for reading from and/or writing to an RFID tag. A processor and a memory process information read from an RFID tag to provide a message based thereon by a visual and/or an audible message.

US 20060032923-A1 provides a system for dispensing pharmaceuticals or other material dispensed in prepackaged containers. The container includes a symbol such as a barcode to identify the contents of the container. The system uses a label having a first portion having an outer edge and a second portion that extends out from one side and above the top of the first portion. The second portion includes an indicium such as a barcode that is printed on the second portion that describes the desired contents of a container on which the label is intended. The symbol and the indicium are electronically read after the label is affixed to the container to determine if the label is on a container having the identified contents.

US 7114654-B2 discloses an RFID encoder that is used in conjunction with a barcode print. The RFID encoder utilizes information obtained from a data stream from a host computer, from a corresponding barcode label, or other source to program an RFID label. The programmed label can then be applied with an integrated applicator or an external applicator. The RFID encoder can also verify that an RFID tag or label has been properly encoded and has the same content as the corresponding barcode label. The RFID can further verify that the barcode has been properly printed. If both barcode and RFID tag contain the correct data, both types of labels are attached to a package, enabling the package to be read optically and with radio frequency signals.

US 6371375-B1 discloses a system for storing and retrieving data. The system comprises a memory device such as a radio frequency tag having a memory for storing the data, a first identifier stored in the memory of the memory device, and a machine-readable symbol

associated with the memory device, where at least a portion of the machine-readable symbol encodes a second identifier logically associable with the first identifier. The machine-readable symbol may, for example, be printed on the memory device, or may be carried by a container that also carries the memory device. The data stored in the memory device may include data
5 related to the container or items carried by the container. The system of this patent is not intended for the monitoring and labelling of medical or pharmaceutical products. Likewise, this patent neither performs a comparison of the information included in the machine-readable symbol and in the RFID tag, to check if they coincide.

US 6830181-B1 provides a system and method which utilize a dual function reader device,
10 which may be a hand-held inventory control device, which first performs an optical read of an optical bar code on a carrier unit, then based on the identification or other information obtained from the optical read a RF read is made of a RF tag attached to, or within, the carrier unit. An indicator light on the carrier unit illuminates when the optical read is completed, which allows an operator to visually verify that the optical read has transpired for
15 the desired carrier unit. The RF tag provides data regarding the inventory of the goods stored within, or on, the carrier unit, the temperature of the goods, the shelf-life of the goods, the source and/or destination of the carrier unit and/or the goods, or other information. Data can also be written to the RF tag by the reader. This patent does not perform a comparison of the information included in the optical bar code and in the RFID tag, to check if they coincide.

20 Accordingly, there is a need for new methods, systems and devices for monitoring and labelling biological and pharmaceutical products.

Description of the Invention

To that end, present invention provides according to an aspect a method for monitoring and labelling biological and pharmaceutical products. The method comprises reading (at least
25 one) optical tag attached to a biological or pharmaceutical product via a device including an optical reader (e.g. a camera) with computer vision capabilities (e.g. a computer vision software/program), the optical tag including information that define/describe the biological or pharmaceutical product; and reading a RFID tag attached to the biological or pharmaceutical product via a RFID reader, the RFID tag storing in a memory thereof at least one unique
30 identifier or at least one unique identifier and information of the biological or pharmaceutical product.

The method also comprises: comparing, by a processor, the information read from the optical and RFID tags; determining that the compared information, totally or partially, coincides or not based on a result of the comparison; emitting a first indication signal if the information coincides or a second indication signal if the information does not coincide; and determining,
5 by the processor, whether additional information included in the optical tag has to be added to the memory of the RFID tag.

In the cited comparison step, the processor can determine whether all or only part of the information included in the optical tag should be compared with the information read from the RFID tag.

10 In some embodiments, the method can also record the information read from both tags in an external memory or database.

Also, in some embodiments, the processor can compare the information of the RFID tag with information stored in a memory of a computing system and determine if the information stored in the memory of the computing system has to be added to the memory of the RFID
15 tag based on a result of said comparison.

The information included in the optical tag and the RFID tag can comprise one or more of the following: patient name, blood type, medical history, product information, dosage, traceability data, prescription, product control data, or a combination thereof, among others.

The optical tag can be a barcode, a data matrix, an image or a pictogram, among others.

20 In an embodiment, in particular when the determining step has established that additional information has to be added to the memory of the RFID tag, the additional information can be directly included into said memory or alternatively the additional information can modify or overwrite previously stored information in the memory of the RFID tag.

In an embodiment, the readings of the tags are performed simultaneously during labeling of
25 the biological or pharmaceutical product. Likewise, the reading of the optical tag and of the RFID tag can be simultaneously performed.

The first and second indication signals can be optical and/or acoustic signals. Particularly, the two signals are different, thus it is easier for a user to recognize if the information matches or not.

According to another aspect, present invention also provides a system for monitoring and labelling biological and pharmaceutical products. The proposed system comprises a device that includes an optical reader such as a camera with computer vision capabilities and a RFID reader, and a computing system operatively connected to the device and including a memory and at least one processor.

According to the proposed system, the device is configured to read an optical tag attached to a biological or pharmaceutical product via the optical reader, the optical tag including information that defines the biological or pharmaceutical product. The device is also configured to read a RFID tag attached to the biological or pharmaceutical product via the RFID reader, the RFID tag storing in a memory thereof at least one unique identifier or at least one unique identifier and information of the biological and pharmaceutical product.

The processor(s) can be configured to execute/apply one or more algorithms to determine whether all of the information or only part of the information included in the optical tag must be compared with the information included in the RFID tag. Moreover, the processor(s) determine that the compared information (totally or partially) coincides or not based on a result of the comparison, and emit a first indication signal if the information coincides or a second indication signal if the information does not coincide. Besides, the processor(s) determine whether additional information included in the optical tag has to be added to the memory of the RFID tag.

In yet another aspect, present invention also provides a device for monitoring and labelling biological and pharmaceutical products. The proposed device has an optical reader with computer vision capabilities adapted to read an optical tag attached to a biological or pharmaceutical product, the optical tag including information about said biological or pharmaceutical product; a RFID reader adapted to read a RFID tag attached to said biological or pharmaceutical product, the RFID tag storing in a memory thereof at least one unique identifier or at least one unique identifier and information of the biological and pharmaceutical product; and a processing unit adapted to execute/apply one or more algorithms to: compare the information read from the tags; determine that the compared information, totally or partially, coincides or not based on a result of the comparison; emit a first indication signal if the information coincides or a second indication signal if the information does not coincide; and determine whether additional information included in the optical tag has to be added to the memory of the RFID tag.

In a particular embodiment, the device also has a counter support to hold the biological or pharmaceutical product. Moreover, the device may also have a motion sensor to detect when the biological or pharmaceutical product is placed on said counter support, so the monitoring process can start autonomously and automatically upon said detection is made.

- 5 Thus, the present invention provides a new technology/architecture for automating the monitoring of biological and pharmaceutical products during their transport by means of labelling said products (blood components, muscle tissues, organs, medicines, drugs, etc.) with RFID tags and a multi-barcode or other equivalent readable data matrix label.

- Furthermore, the present invention is capable of reading a multi-barcode or data matrix label
10 (i.e. an optical tag) attached to a product and to record that information read in a RFID tag, and of verifying that the information in the multi-barcode or data matrix label is already stored, at least in part, in the RFID tag (to be used as a redundancy checkpoint).

Other features of the invention appear from the following detailed description of the invention.

Brief description of the Drawings

- 15 The foregoing and other advantages and features will be more fully understood from the following detailed description of the invention with reference to the accompanying drawings, to be taken in an illustrative and not limitative, in which:

Fig. 1 is a flow chart illustrating an embodiment of a method for monitoring and labelling biological and pharmaceutical products.

- 20 Fig. 2 is a flow chart illustrating another embodiment of a method for monitoring and labelling biological and pharmaceutical products.

Detailed Description of the Invention

- With reference to Fig. 1 therein it is illustrated a first embodiment of the proposed method. According to this embodiment, at step 101, an optical tag (e.g. a barcode, a data matrix, an
25 image, a pictogram, etc.) attached to a biological or pharmaceutical product such as blood components, muscle tissues, organs, medicines, drugs, etc. is read via a device including an optical reader with computer vision capabilities. At step 102, a RFID tag attached to the biological or pharmaceutical product is read via a RFID reader.

The optical tag includes/stores information about or that defines the biological or pharmaceutical product. Likewise, the RFID tag has associated thereto a unique identifier and can include/store in a memory thereof information or data about the product. For example, the information can comprise a patient name, blood type, medical history, product information, dosage, traceability data, prescription, product control data, etc.

At step 103, the information read from both tags is compared by a processor. In this case, an algorithm or software particularly determines whether all or only part of the information included in the optical tag must be compared with the information included in the RFID tag. The result of the comparison determines if the compared information coincides or not. If the information coincides, a first optical and/or acoustic signal (step 105) is emitted. On the contrary, if the information does not coincide, a second optical and/or acoustic signal (step 106), particularly different to the first indication signal, is emitted. For example, LEDS and/or a code of colors can be used to indicate the coincidence or not coincidence of the compared information. An audible alarm could be equally used.

With reference to Fig. 2 therein it is illustrated a second embodiment of the proposed method. In this case, different to the first embodiment, an algorithm or software implemented/executed in a processor further determines, step 207, whether additional information included in the optical tag has to be added to the RFID tag. In this embodiment, it is possible to perform stages 205/206 and 207 in reverse order. That is, first it can be decided that additional information has to be added to the RFID tag and then the indication showing that the compared information coincides or not be emitted.

It should be noted that both embodiments described above could be complementary to each other. That is, the proposed method can perform the different steps indicated in each of the above described embodiments.

It should be also noted that in some embodiments the RFID tag can only have stored in its memory a unique identifier. Consequently, in this case, the comparison step will firstly determine that the compared information does not coincide. Later, the determining step can establish that additional information included in the optical tag has to be added to the memory of the RFID tag. So, when new readings of the tags are made, the processor will have to further check whether or not the information stored in both tags matches.

The cited processor can be included in a computing system (e.g. a PC, a cloud server, a smartphone, etc.) remote to the device and connected to the latter, either wirelessly or by cable, or can be included in the device itself. That is, in this latter case the device itself includes a processing unit to execute/perform the different method steps. In either case, a user interface can show the details of the different processes executed.

In any of the described embodiments, the reading of the optical tag and of the RFID tag can be performed simultaneously or one after the other.

The device (not shown in the figures) as indicated above includes an optical reader, for example a camera (digital or analogic having a digital converter), with computer vision capabilities, and a RFID reader. The optical reader is capable of capturing both text and barcodes (or data matrix) from the optical tag. The computer vision capabilities, for example implemented as computer vision software, allow the identification of the pixels in an image taken by the optical reader as barcodes or text and to perform a digital conversion of that data. The RFID reader is able to read and write information on/from the RFID tag. The RFID particularly operates under the ITU RFID standard and range of frequencies.

Particularly, the device also includes a counter support (e.g. a flat surface) to hold the labelled biological or pharmaceutical product. The device can also has an arm to hold the optical reader at a distance from the counter support, in a perpendicular position from the surface of the counter from which the whole surface (or a part of it) can be captured. Optionally, the counter support may have a line of LED lights to show the extension of the surface that is inside the optical reader focus.

The device may also include a motion sensor to detect when the product has been placed in the counter support, so the different cited processes start autonomously and automatically. The communication between the RFID reader and motion sensor is particularly wireless.

The device includes also a power supply unit or batteries for power feeding thereof and may also include other networking components such as cables, software, wireless router, etc. that allow the device to communicate with the remote computing system, sending and receiving information or a sequence of commands.

The cited user interface, which can be included in the remote computing system or in the device itself, provides a configuration panel allowing a user to apply the following restrictions:

- i. *Selection of information*: the user can decide to write or validate part of the information in the optical tag (i.e. just one barcode out of several, the information placed in the upper corner of the optical tag, etc.).
- 5 ii. *Writing*: the user can transform and code some information in the optical tag or simply add new information in the memory of the RFID tag (i.e. if the word “infected” is written with words on the optical tag, a bit in a certain position of the memory of the RFID tag is set to “1”).
- 10 iii. *Field Selection (in the RFID tag)*: the user can decide if the operation (validation or writing) is to be applied on the total extension of the memory or to some positions. In the case of writing, the new information can optionally overwrite previous existing information stored in the selected part of the memory or the memory can be totally erased before writing.

The above-described embodiments of the present invention are merely meant to be illustrative and not limiting. It will thus be obvious to those skilled in the art that various
15 changes and modifications may be made without departing from this invention in its broader aspects. Therefore, the following claims include all such changes and modifications as fall within the scope of this invention.

CLAIMS

1. A method for monitoring and labelling biological and pharmaceutical products, the method comprising:

reading at least one optical tag attached to a biological or pharmaceutical product via a device including an optical reader with computer vision capabilities, the at least one optical tag including information about the biological or pharmaceutical product;

reading a RFID tag attached to the biological or pharmaceutical product via a RFID reader, the RFID tag storing in a memory thereof at least one unique identifier or at least one unique identifier and information of the biological or pharmaceutical product;

comparing, by a processor, the information read from the optical and RFID tags;

determining that the compared information, totally or partially, coincides or not based on a result of the comparison;

emitting a first indication signal if the information coincides or a second indication signal if the information does not coincide; and

determining, by the processor, whether additional information included in the optical tag has to be added to the memory of the RFID tag.

2. The method of claim 1, wherein the information included in the optical tag and the RFID tag comprises one or more of: patient name, blood type, medical history, product information, dosage, traceability data, prescription, product control data, or a combination thereof.

3. The method of any of previous claims, further comprising:

comparing, by the processor, the information of the RFID tag with information stored in a memory of a computing system; and

determining if the information stored in the memory of the computing system has to be added to the memory of the RFID tag based on a result of said comparison.

4. The method of any of the previous claims, wherein the method is implemented simultaneously during labeling of the biological or pharmaceutical product.

5. The method of any of the previous claims, wherein the optical tag comprises a barcode, a data matrix or a pictogram.

6. The method of claim 1, wherein the first indication signal is an optical and/or an acoustic signal and the second indication signal is an optical and/or an acoustic signal.

7. The method of claim 1 or 6, wherein the first indication signal and the second indication signal are different.

5 8. The method of claim 1, wherein the reading of the at least one optical tag and of the RFID tag is performed simultaneously.

9. A system for monitoring and labelling biological and pharmaceutical products, comprising:

- a device including an optical reader with computer vision capabilities and a RFID reader, said device being configured to:

10 read at least one optical tag attached to a biological or pharmaceutical product via the optical reader, said at least one optical tag including information about said biological or pharmaceutical product; and

read a RFID tag attached to the biological or pharmaceutical product via the RFID reader, the RFID storing in a memory thereof at least one unique identifier or at least
15 one unique identifier and information of the biological and pharmaceutical product; and

- a computing system operatively connected to the device, said computing system including a memory and at least one processor, wherein said processor is configured to:

compare the information read from the optical and RFID tags;

determine that the compared information, totally or partially, coincides or not
20 based on a result of the comparison;

emit a first indication signal if the information coincides or a second indication signal if the information does not coincide; and

determine whether additional information included in the optical tag has to be added to the memory of the RFID tag.

25 10. The system of claim 9, wherein the device further comprises a counter support configured to hold the biological or pharmaceutical product and a motion sensor configured to detect when the biological or pharmaceutical product is placed on said counter support.

11. The system of claim 9, wherein the first indication signal is an optical and/or an acoustic signal and the second indication signal is an optical and/or an acoustic signal.

12. A device for monitoring and labelling biological and pharmaceutical products, comprising:

- an optical reader with computer vision capabilities configured to read at least one optical tag attached to a biological or pharmaceutical product, said at least one optical tag including information about said biological or pharmaceutical product;

5 - a RFID reader configured to read a RFID tag attached to said biological or pharmaceutical product, the RFID storing in a memory thereof at least one unique identifier or at least one unique identifier and information of the biological and pharmaceutical product;

- a processing unit configured to:

- compare the information read from the optical and RFID tags;

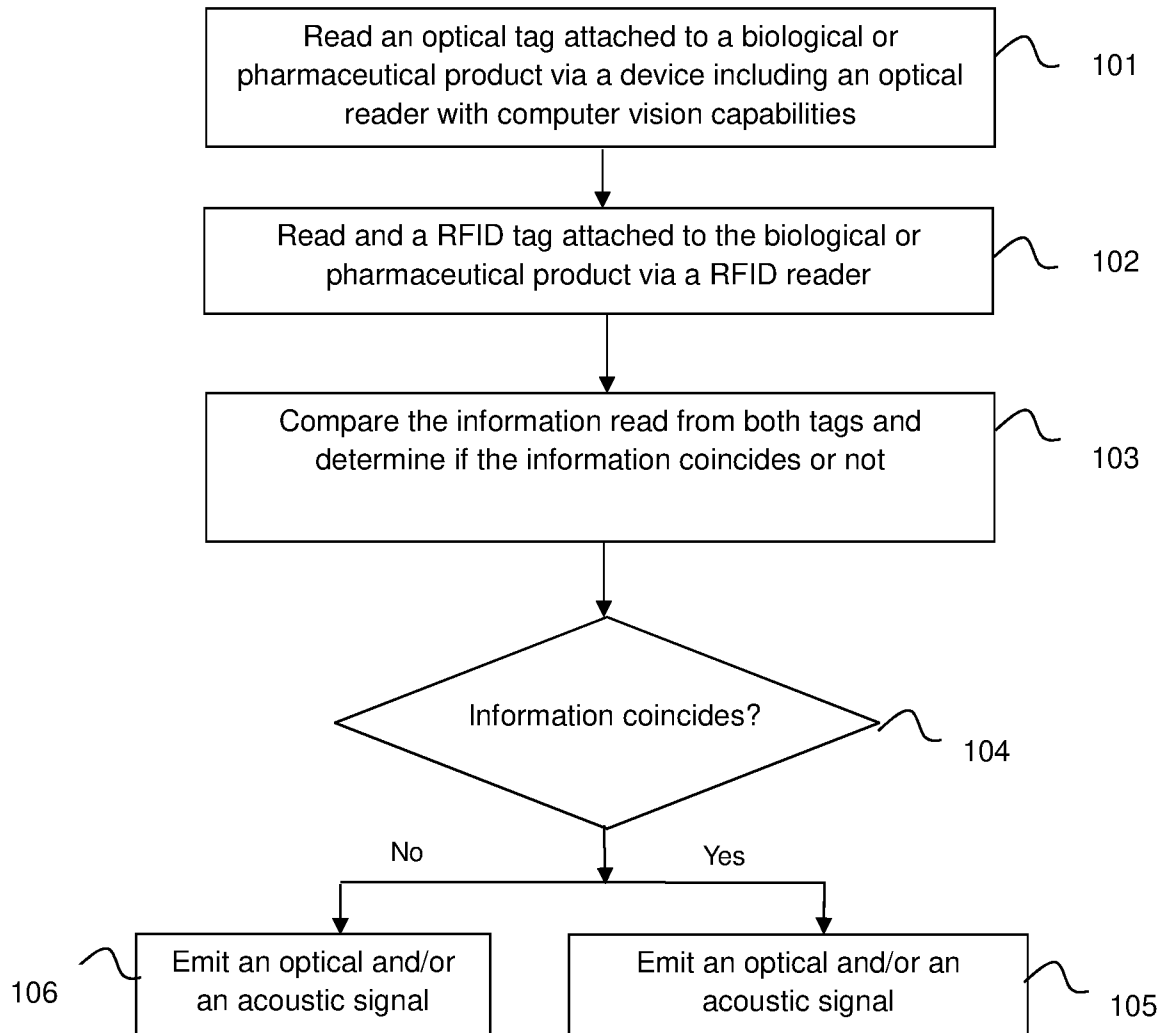
10 determine that the compared information, totally or partially, coincides or not based on a result of the comparison;

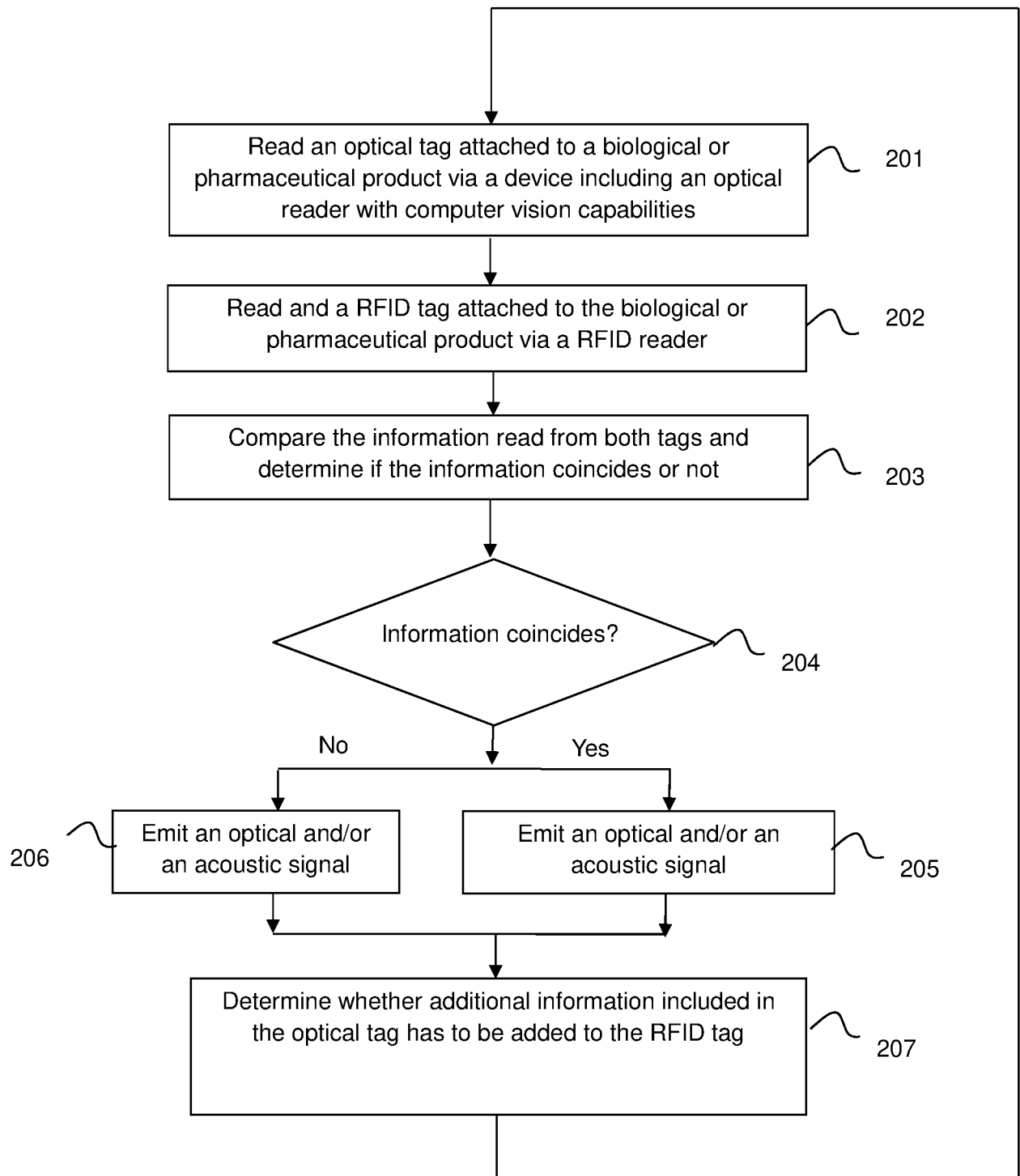
- emit a first indication signal if the information coincides or a second indication signal if the information does not coincide; and

15 determine whether additional information included in the optical tag has to be added to the memory of the RFID tag.

13. The device of claim 12, further comprising a counter support configured to hold the biological or pharmaceutical product and a motion sensor configured to detect when the biological or pharmaceutical product is placed on said counter support.

20 14. The device of claim 12 or 13, wherein the first indication signal is an optical and/or an acoustic signal and the second indication signal is an optical and/or an acoustic signal.

**Fig. 1**

**Fig. 2**

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/058424

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06K7/00 G06K17/00 G06K7/10
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 371 375 B1 (ACKLEY H SPRAGUE [US] ET AL) 16 April 2002 (2002-04-16) column 1, line 23 - line 24 column 3, line 8 - line 10 column 5, line 25 - line 38 column 7, line 46 - line 60 column 8, line 6 - line 16 figures 1-5,7	1-14
Y	US 6 830 181 B1 (BENNETT JAMES D [US]) 14 December 2004 (2004-12-14) column 2, line 61 - column 3, line 5 column 3, line 51 - line 58 column 5, line 24 - line 48 column 6, line 41 - line 44 column 9, line 1 - line 11 figures 1,9 ----- -/--	1-14



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

"&" document member of the same patent family

Date of the actual completion of the international search

3 June 2020

Date of mailing of the international search report

15/06/2020

Name and mailing address of the ISA/

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Authorized officer

Bhalodia, Anil

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/058424

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/221099 A1 (KITAGAWA TORU [JP]) 29 August 2013 (2013-08-29) paragraph [0080] - paragraph [0082] figures 1-6 -----	10,13
A	US 2007/188306 A1 (TETHRAKE STEVEN M [US] ET AL) 16 August 2007 (2007-08-16) paragraph [0027] - paragraph [0028] figure 1 -----	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2020/058424

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