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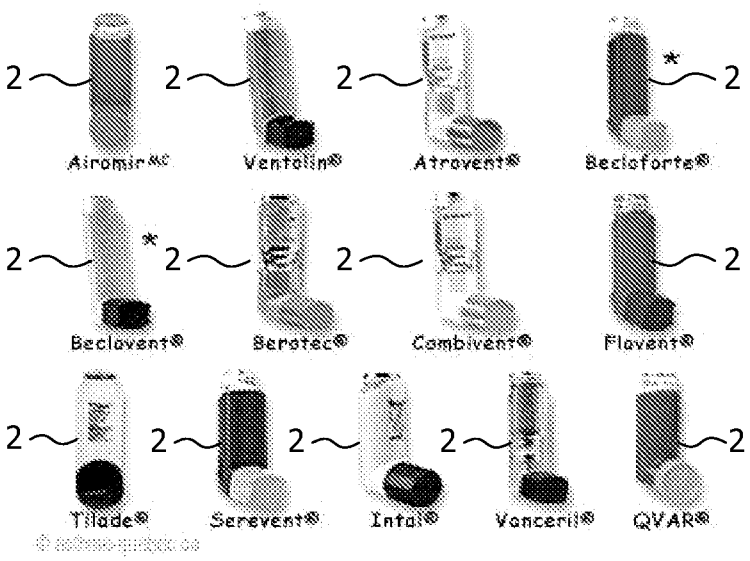
Declarations under Rule 4.17 :

[Continued on next page]

(54) Title: COLOR IDENTIFICATION FOR DRUG DELIVERY SYSTEM



(57) Abstract: A monitoring device includes a housing that is constructed and arranged to be removably attached to a drug delivery device for an inhaled drug. A color detector is operatively associated with the housing and constructed and arranged to detect an identifying color of at least a portion of the drug delivery device when the housing is attached to the drug delivery device and to output color information for use by a processor to, based on the detected color, identify information about the inhaled drug.

FIG. 1

WO 2011/073806 A1

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(Hi))*

Published:

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

COLOR IDENTIFICATION FOR DRUG DELIVERY SYSTEM

[01] The invention relates generally to drug delivery devices and more particularly to a system for identifying a medication based on measured color of the devices.

[02] It is known to deliver medications to patients for treatment of medical conditions using an aerosol medication delivery system. For example, in response to acute asthma episodes, a patient may use such a delivery system to deliver a bronchodilator such as albuterol. Typically, such a system would include a metered dose inhaler (MDI), which may be used with or without a spacer. The MDI itself is an L-shaped device that includes a pressurized medicine container and a canister holder that generally includes a mouthpiece. To operate the MDI, a user presses down on the container, causing the medicine to be expelled through the mouthpiece for inhalation by the patient. For systems that include a spacer, the spacer provides additional air volume to allow better mixing of the aerosolized medicine with ambient air prior to inhalation.

[03] A similar device is the dry powder inhaler (DPI). In a DPI, a measured dose of powdered medication may be delivered without any propellant, the user's inspiratory flow providing the air volume for pulling the powdered medication into the user's lungs. In a typical device of this type, actuating the DPI loads a measured volume of powdered medication into a dosing chamber. The user then inhales, drawing air and the medication into his or her lungs. For children in particular, DPI devices may be easier to use as, unlike MDI devices, there is no need to coordinate actuation with inspiration.

[04] Nebulizers may also be used for delivery of medications to a patient's lungs. A nebulizer includes an air source and a fluid medicine reservoir. The air source is used to provide a strong flow of air through the fluid, aerosolizing it for delivery to the patient. In general, nebulizers are bulky and inconvenient compared to MDI and DPI devices.

[05] It may be useful for an administering medical team to monitor the use of inhaled medications for compliance with the prescribed regimen.

[06] A monitoring device includes a housing that is constructed and arranged to be removably attached to a drug delivery device for an inhaled drug. A color detector is operatively associated with the housing and constructed and arranged to detect an identifying color of at least a portion of the drug delivery device when the housing is attached to the drug delivery device and to output color information for use by a processor to, based on the detected color, identify information about the inhaled drug.

[07] Another aspect of an embodiment of the present invention includes a broadband light source for illuminating the drug delivery device and a color-sensitive detector to detect the identifying color.

[08] Another aspect of an embodiment of the present invention includes multiple, relatively narrow-band light sources for sequentially illuminating the drug delivery device, a color-insensitive detector, and analyzing functionality to combine detected information to determine the identifying color.

[09] As will be appreciated by those of skill in the art, a color detecting device in accordance with an embodiment of the invention may find application in medicine delivery systems other than inhaled drug delivery systems. In this regard, such devices may include sensors similar to those described herein with respect to inhaled drug delivery systems for detecting color information relating to identification of a drug type or dose. Such sensors may be used, for example, in collecting, storing and/or reporting compliance by a patient.

[10] These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. In one embodiment of the invention, the structural components illustrated herein are drawn to scale. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not a limitation of the invention. In addition, it should be

appreciated that structural features shown or described in any one embodiment herein can be used in other embodiments as well. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and in the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

[11] FIG. 1 illustrates a number of different MDIs, each having differing coloration for use with a device in accordance with an embodiment of the invention;

[12] FIG. 2 illustrates a number of different DPIs, each having differing coloration for use with a device in accordance with an embodiment of the invention;

[13] FIG. 3 illustrates an MDI along with a spacer for use with a device in accordance with an embodiment of the invention;

[14] FIG. 4 illustrates an MDI and spacer, including a monitor in accordance with an embodiment of the invention;

[15] FIG. 5 schematically illustrates a sensor for use in a monitor in accordance with an embodiment of the invention;

[16] FIG. 6 schematically illustrates a scanning color sensor for use in a monitor in accordance with an embodiment of the invention; and

[17] FIG. 7 schematically illustrates a white light sensor for use in a monitor in accordance with an embodiment of the invention.

[18] As described above, drug delivery systems for inhaled medicines include, but are not limited to, MDI, DPI and nebulizers. In general, manufacturers of such delivery systems use color information to inform a user regarding the nature of the medication. Color information may be relevant, for example, to type, amount, and/or strength of medication. In both the United States and the European Union, pharmaceutical packaging is regulated, and a manufacturer may not, in general, make changes to the packaging, including the plastic material, without licensing approval. As a result, color information should be a relatively stable identification method for most drug delivery systems.

[19] In this regard, the regulator ensures that colors are approved and controlled to ensure that there is the minimum risk of confusion on the part of the public or medical

professionals. For each manufacturer colors will generally be different for each type of drug, though drugs of the same type from different manufactures may have similar but not identical colors, e.g., bronchodilators may be supplied in blue delivery systems, while steroids may be supplied in brown delivery systems.

[20] FIG. 1 shows 13 different MDIs 2, each MDI 2 containing a different medicine. As may be seen, each is of a different color, though the colors are rendered in grey scale for the purposes of this application. By way of example only, in the original, full-color figure, the three along the right hand side are different shades of red and orange, while the upper left hand corner MDI is blue and the lower left hand corner is yellow. Others in the FIG. each have their own distinctive coloration.

[21] Likewise, FIG. 2 illustrates three different DPIs 4, each a different color. By way of example, the three DPIs are green, red and purple, from left to right. In nebulizers, such as I-neb® from Philips Respironics, color of a portion of the metering chamber and/or a removable control disc can inform a user regarding the amount of medication that will be provided with each application.

[22] FIG. 3 illustrates an MDI 2 inserted into a spacer 8. FIG. 4 illustrates a similar MDI 2 inserted into a spacer 8 that incorporates a monitor 10 in accordance with an embodiment of the invention.

[23] A monitor 10 in accordance with an embodiment of the invention is a non-contact device that does not generally engage directly with any drug product, thereby reducing likelihood of contamination when the drug canister is changed, nor does it generally require cleaning to remove drug residue. In this regard, a non-contact color recognition system may be permanently or removably mounted to the drug delivery device.

[24] FIG. 5 illustrates an embodiment in which the monitor 10 includes an opening 12 such that a portion 14 of the drug delivery device is exposed to the monitor when the device is inserted. A color detecting device 16 captures color information from the portion 14, and may provide the color information to a memory 18, which may be internal to the monitor 10, or may be associated with a separate device.

[25] In an embodiment illustrated in FIG. 6, the monitor includes three LEDs, 20, 22, 24, which may be, for example, red, blue and green respectively. In this approach, the LEDs

20, 22, 24 are controlled by a controller and powered with a power source, not shown. A light detector 26, such as a photodiode, is positioned to receive light reflected from the portion 14 of the drug delivery device, when illuminated by the LEDs. It is useful to ensure that the detector 26 does not receive light directly from the LEDs but rather is shielded so that it receives light primarily from the target portion 14. The controller sequentially activates the LEDs, thereby performing a color sequential scan. The received light at the detector 26 for each color signal may then be combined to produce color information indicative of drug information.

[26] As will be appreciated, similar methods may be used based on different LED colors, and the scope of the present invention should not be considered to be limited to an RGB system. Likewise, though illustrated as first reflecting from a remote surface of the monitor, the LED light need not do so, and may directly impinge on the portion 14 of the surface of the drug delivery device.

[27] In an alternate approach, illustrated in FIG. 7, the LEDs of the monitor 10' may be replaced with a white light source 30 and the detector 26 may be replaced with a color detector 26', such as a CCD. For example, the color detector 26' may be a CCD using a color filter array such as a Bayer filter, though other color filter arrays may find application within the scope of the present invention.

[28] In this arrangement the color detector receives light from the white light source reflected from the inhaler body, the controller then analyzes the signal generated by the detector to determine the color of the inhaler. When the controller has determined the color of the inhaler it can be recorded in the device memory 18 as part of the treatment compliance record.

[29] The color recorded in the treatment compliance record can then be compared with a master list of inhaler colors and the type of inhaler identified to the clinician or patient. This identification may be completed in the device or remotely in a PC, when the data is downloaded or as part of an internet based system incorporating a server. Alternately, a function-specific reader could be employed. The download functionality may be via a plug-in connector such as USB or other bus, or may be wireless, for example with an RFID-type reader or other radio device.

[30] In an embodiment, the monitor 10 may further include a sensor to determine when a dose is administered. Such a sensor may be based on a number of different sensing approaches. In an embodiment, a circuit may be completed each time the inhaler is actuated, incrementing a use count to be stored in the memory 18. While the specifics of such a detector are not critical to the present application, one of skill in the art would appreciate that a variety of approaches are available. For example, airflow through a portion of the delivery device could be detected, sound or pressure sensors could be used, or optical detectors could be used.

[31] In embodiments, the monitor 10 may include functionality for discriminating based on the detected color, and outputting identifying information for the monitored drug delivery system. This may include, for example, stored color values associated with particular drug delivery devices and processing capability for comparing detected color with the stored color values. Likewise, the monitor 10 may include alarm functionality wherein when the detected color does not match a preselected color associated with a patient's prescribed medication, the alarm is sounded to warn the patient not to use the medication.

[32] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

CLAIMS:

1. A monitoring device comprising:

a housing, constructed and arranged to be removably attached to a drug delivery device for an inhaled drug; and

a color detector, operatively associated with the housing and constructed and arranged to detect an identifying color of at least a portion of the drug delivery device when the housing is attached to the drug delivery device and to output color information for use by a processor to, based on the detected color, identify information about the inhaled drug.

2. A device as in claim 1 further comprising:

a detector, operatively associated with the housing and constructed and arranged to detect actuation of the drug delivery device and to output a detection signal to the processor in response.

3. A device as in claim 1, wherein the color detector comprises:

a plurality of light sources that, in use, produce respective different colored light;

a photodetector;

the light sources and photodetector being respectively arranged such that, when the housing is attached to the drug delivery device, light from the light sources reflects from the portion of the drug delivery device, and reflected light impinges on the photodetector;

a controller, configured and arranged to controllably operate the light sources in sequence; and

an analyzer, configured and arranged to combine sequentially detected signals from the photodetector and to mix them to produce the color information.

4. A device as in claim 1, wherein the color detector comprises:

a broadband light source; and

a color-sensitive photodetector.

5. A device as in claim 4, wherein the color-sensitive photodetector comprises a CCD.

6. A device as in claim 5, wherein the CCD comprises a color filter array.

7. A device as in claim 1, further comprising, a memory, in communication with the color detector, the memory having stored therein a plurality of stored color information data, each stored color information datum associated with a particular inhaled drug, and wherein the processor is configured and arranged to compare the detected color with the stored color information data to identify information about the inhaled drug.

8. A device as in claim 1, further comprising an alarm, wherein when the identified information about the inhaled drug does not correspond to a preselected inhaled drug prescribed to a user, the alarm produces an audible or visible indicator.

9. A method of monitoring use of a drug delivery device, comprising:

detecting color information from the drug delivery device;

determining from the detected color information, drug information relating to a type, dosage amount and/or strength of a drug contained in the drug delivery device; and

storing the drug information.

10. A method as in claim 9, further comprising:

after the storing, transmitting the drug information to a storage location remote from the drug delivery device.

11. A method as in claim 10, wherein the storage location remote from the drug delivery device is Internet accessible.

12. A method as in claim 9, wherein the detecting the color of the drug delivery device further comprises:

sequentially illuminating a portion of the drug delivery device with different colored light; and

analyzing detected sequentially reflected light from the drug delivery device to produce the color information.

13. A method as in claim 9, wherein the detecting the color of the drug delivery device further comprises:

illuminating a portion of the drug delivery device with broadband illumination; and

detecting the color information with a color-sensitive detector.

14. A method as in claim 13, wherein the color-sensitive detector comprises a CCD.

15. A method as in claim 9, further comprising:

comparing detected color information to an expected color information corresponding to a particular drug, and when the detected color information does not match the expected color information, indicating the mis-match to a user.

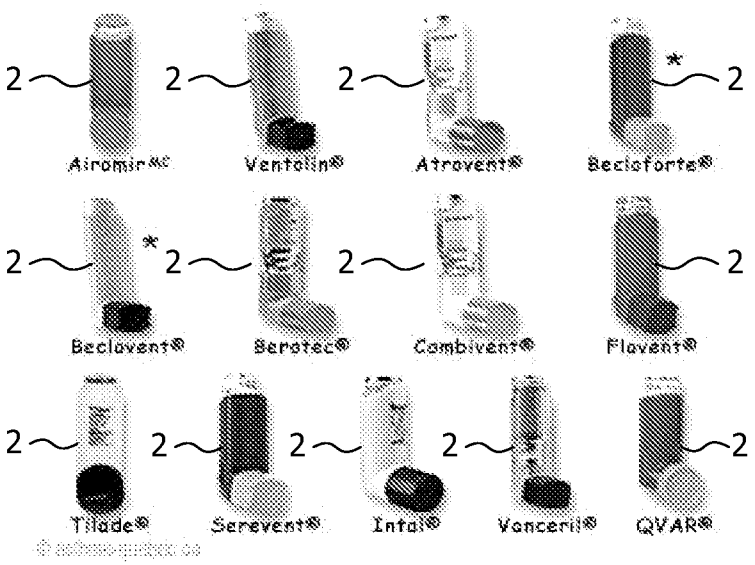

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FIG. 1

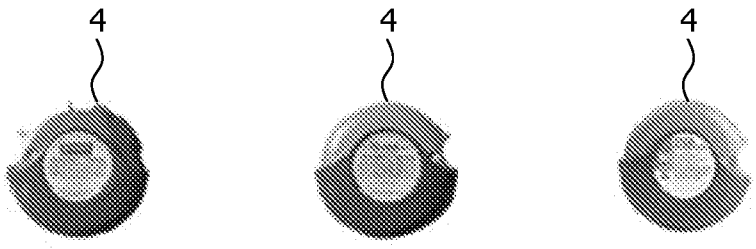
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FIG. 2

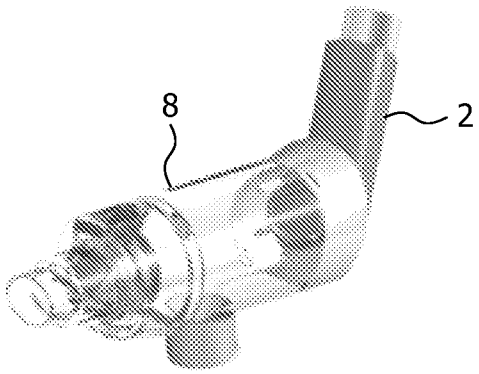

FIG. 3

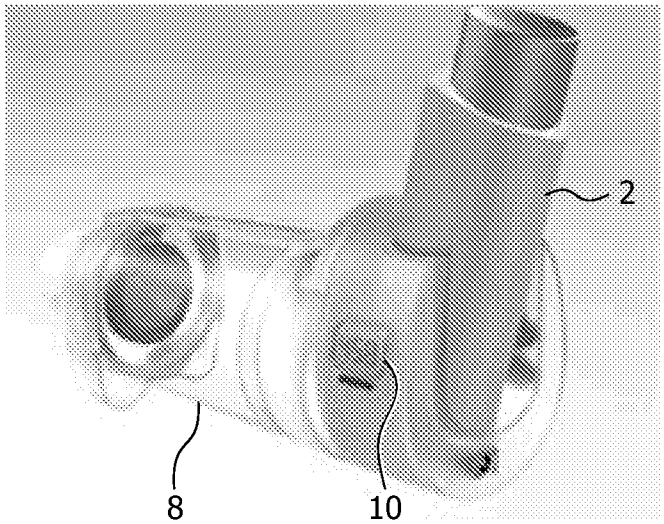

FIG. 4

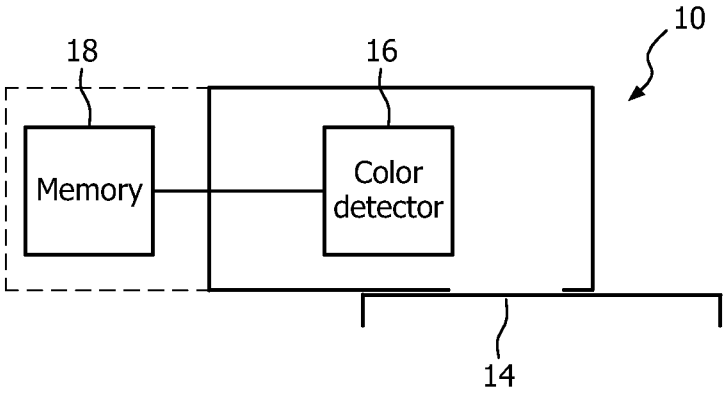

FIG. 5

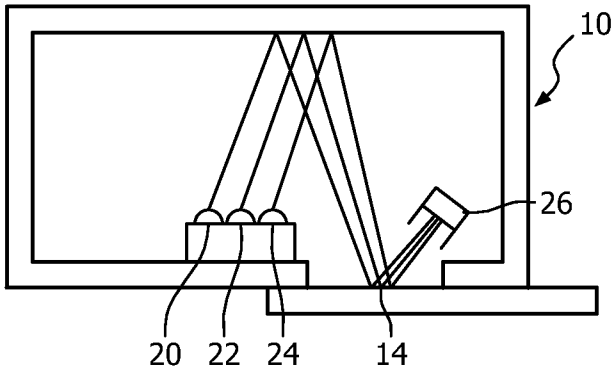

FIG. 6

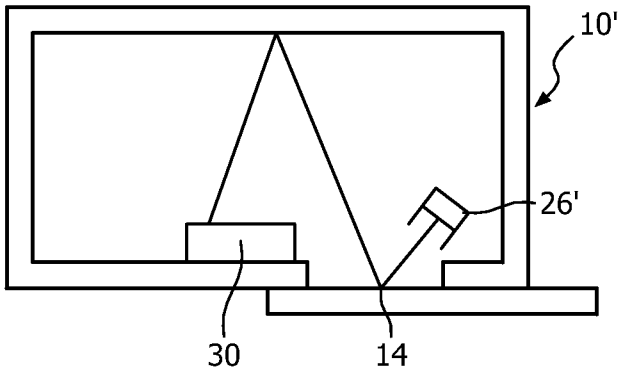

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB201Q/055095

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M15/00
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)
A61M

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 263 068 A (MINNESOTA MINING & MFG [US]) 14 July 1993 (1993-07-14) page 6, line 9 - page 6, line 3; figures page 10, line 9 - page 10, line 17	1,2, 8-11, 15
X	WO 2006/129301 A2 (SPECTRUM DYNAMICS [IL]; R0USS0 BENNY [IL]; BEN-HAIM SHL0M0 [GB]; BR0NS) 7 December 2006 (2006-12-07) page 100, line 29 - page 102, line 23; figures 16A, 16B page 81, line 9	1,3-7, 9-15
A	US 2007/181119 Al (WEINSTEIN ROBERT E [US] ET AL) 9 August 2007 (2007-08-09) * abstract; figures	1

-/ -

[X] Further documents are listed in the continuation of Box C. [X] 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 document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2011	03/03/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Val fort, Cyri l

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INTERNATIONAL SEARCH REPORT

International application No
PCT/ I B201Q/055095

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/5 1360 AI (ASTRA PHARMA PROD [GB] ; ASTRA AB [SE] ; FRI D PER [SE] ; JANSEN ROBERT [G) 19 November 1998 (1998 - 11- 19) * abstract ; f i gures -----	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2010/055095

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