

(19) **DANMARK**

(10) **DK/EP 3941652 T3**



(12) **Oversættelse af
europæisk patentskrift**

Patent- og
Varemærkestyrelsen

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- (51) Int.Cl.: **B 08 B 15/02 (2006.01)**
- (45) Oversættelsen bekendtgjort den: **2023-02-20**
- (80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2022-11-16**
- (86) Europæisk ansøgning nr.: **20711576.7**
- (86) Europæisk indleveringsdag: **2020-03-12**
- (87) Den europæiske ansøgnings publiceringsdag: **2022-01-26**
- (86) International ansøgning nr.: **EP2020056720**
- (87) Internationalt publikationsnr.: **WO2020233854**
- (30) Prioritet: **2019-05-18 DE 102019207280**
- (84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**
- (73) Patenthaver: **Syntegon Technology GmbH, Stuttgarter Straße 130, 71332 Waiblingen, Tyskland**
- (72) Opfinder: **METZGER, Simon, Norbertusweg 1, 89297 Roggenburg, Tyskland**
MARTIN, David, 78 Petterson Dale Coxhoe, Durham DH6 4HA, Storbritannien
HAAG, Heiko, Radwang 5, 91550 Dinkelsbuehl, Tyskland
GRAF, Sebastian, Zum Osterfeld 15, 74589 Satteldorf, Tyskland
WOOD, Nigel, Marwood Lodge, Marwood DL128SA Barnard Castle, Durham DL12 8SA, Storbritannien
- (74) Fuldmægtig i Danmark: **Budde Schou A/S, Dronningens Tværgade 30, 1302 København K, Danmark**
- (54) Benævnelse: **Anlæg til håndtering af følsomme produkter, især emballeringsanlæg**
- (56) Fremdragne publikationer:
EP-A2- 1 460 126
WO-A1-2017/072591
WO-A2-2018/050889
DE-A1- 19 947 786

Description

Prior art

5 The present invention relates to a system for handling sensitive products, in particular liquid or powdered pharmaceuticals or the like, and in particular to a packaging system for filling and sealing containers for pharmaceuticals.

10 When handling pharmaceutical products, increased purity requirements must be met when filling and sealing containers filled with such pharmaceutical products. Such a packaging system is known from DE 199 47 786 A1, for example. The packaging system comprises a cleanroom
15 designed as an isolator with the strictest requirements. It is also known that the air in such cleanrooms is monitored in order to avoid microbiological contamination of the product to be filled. For this purpose, Petri dishes with a corresponding culture medium are arranged in the cleanroom. Such Petri
20 dishes are handled manually by means of a glove port in the isolator. If necessary, the Petri dish is also manually labeled in order to be able to assign the Petri dish to a filled batch of the product. However, manual intervention in the packaging system increases the risk of an error occurring during the manual handling. Also, Petri dish handling cannot be carried out reproducibly due to the human factor. Human errors that occur are, for example, opening the Petri dish too early or too late or incorrectly
25 positioning the Petri dish within the cleanroom. Other sources of error are incorrect or incomplete labeling. It would therefore be desirable to have an improved packaging system.

30 EP 1 460 126 A2 and WO 2018/050 889 A2 each disclose a system having features of claim 1. EP 1 460 126 A2 discloses a system for handling sensitive products according to the preamble of claim 1.

Disclosure of the invention

35 The system according to the invention for handling sensitive products having the features of claim 1 has the advantage that safe and simple handling is possible through automation. In this way, human errors in the microbiological air monitoring within the system can be avoided. Manual

interventions by a person from outside the system are no longer necessary. If pharmaceuticals are filled, for example, this results in a significant reduction in a pharmaceutical risk for the overall process within the system. It is also possible to rule out possible injuries to a user which could occur when using a glove port to reach into the interior of the system. This is achieved according to the invention by the fact that the system comprises an enclosed space in which the sensitive products are handled and a device for monitoring the air in the enclosed space. The device for monitoring the air comprises a measuring point and at least one Petri dish. The Petri dish is arranged inside the enclosed space and comprises a lower receptacle (dish) and a lid. The system further comprises an automatic handling device, wherein the handling device is designed to automatically remove the lid from the lower receptacle of the Petri dish and put it on. A culture medium or the like is provided in the Petri dish to allow microbiological air monitoring in the enclosed space. For this purpose, the closed Petri dish is automatically brought to the measuring point by means of the automatic handling device, and the lid is removed from the Petri dish and stored at a predetermined storage location. After a predetermined time has elapsed, the lid is then picked up again, placed on the lower receptacle of the Petri dish, and this is brought to a storage location in a magazine, for example. If necessary, a new Petri dish is automatically removed and positioned on the measuring point, the lid of the new Petri dish is removed and a second measurement is carried out. Thus, according to the invention, the microbiological air monitoring can be carried out fully automatically inside the system, without a user having to carry out Petri dish handling from the outside by using a glove port or the like.

According to the invention, the automatic handling device is designed to carry out further handling steps, in particular transport steps for containers. This makes it possible for the automatic handling device to take on additional tasks besides air monitoring. For example, containers into which a product is to be filled can be transported inside the enclosed space between a filling station and a sealing station for the container. Alternatively or additionally, the automatic handling device can also transport empty and/or filled containers from a storage location or to a storage location.

The dependent claims show preferred developments of the invention.

5 The system preferably comprises a large number of Petri dishes. The large number of Petri dishes are preferably provided in an air sampler having a collecting head and a magazine for the Petri dishes. The automatic handling device can preferably also automatically remove the collecting head of the air sampler and put it on. This allows the degree of automation to be increased further.

10 The system particularly preferably further comprises a filling station for filling the sensitive products into containers and a sealing station for sealing the filled containers. The automatic handling device is particularly preferably designed to transport the containers from the filling station to the sealing station. The containers can be transported individually, or
15 alternatively multiple containers can be transported at the same time. In this case, an additional format device can be provided in order to accommodate multiple containers at the same time.

20 The automatic handling device is particularly preferably a robot. The robot is preferably a 6-axis robot. The robot further preferably has a gripper with at least two gripping jaws. Containers or the Petri dishes can be clamped between the two gripping jaws. More preferably, the robot can change the gripper so that different gripping jaws can be attached to the robot. This
25 may be necessary, for example, when the automatic handling device is used both for monitoring the air by means of the Petri dishes and for transporting containers.

30 According to a further preferred embodiment of the present invention, the system further comprises an identification device. The identification device is designed to identify Petri dishes and to assign a measuring time during which the Petri dish was open, in order to carry out microbiological air monitoring, to this Petri dish.

35 Preferably, each Petri dish has an individual, optical identification mark. This can be a barcode or an identification number or the like, for example. The identification device also has an optical recognition device. For example, this can be a scanner or a camera or the like.

The enclosed space of the system is particularly preferably designed in such a way that the system has an isolator system or restricted-access barrier system (RABS). Thus, the system according to the invention is a cleanroom system with increased requirements for air quality. This is necessary for example when handling pharmaceuticals or fine chemicals or the like.

Brief description of the drawings

A system for handling sensitive products according to a preferred embodiment of the invention is described in detail below. In the drawings:

Fig. 1 is a schematic, perspective view of a system according to a preferred embodiment of the invention and

Fig. 2 to 4 schematically show the automated handling within the system for microbiological air monitoring.

Preferred embodiments of the invention

A filling and packaging system according to a first preferred embodiment of the invention is described in detail below with reference to Fig. 1 to 4.

As can be seen from the schematic view of Fig. 1, the system 1 comprises an enclosed space 2 which is closed off from the surroundings by space walls 20, 21. A plurality of hand ports 8 are provided in the space wall 20 in order to allow gloves (not shown) to be used in the enclosed space 2.

The system 1 is a filling and sealing system for pharmaceutical products and comprises a filling station 10 and a sealing station 11. These are shown only schematically in Fig. 1.

Furthermore, a device 3 for air monitoring is provided for microbiological air monitoring in the enclosed space 2. The device 3 can be seen in detail from Fig. 2 to 4.

The device 3 for air monitoring comprises a magazine 33 having a large number of Petri dishes 30. In this embodiment, exactly three Petri dishes 30 are provided.

5 Each Petri dish 30 comprises a lower receptacle 31 (dish) and a lid 32. A culture medium or the like is introduced into the lower receptacle 31. During the filling and sealing of the pharmaceutical products, the Petri dish is opened so that any germs located in the enclosed space 2 settle in the Petri dish. After the containers have been filled and sealed, this Petri dish
10 can then be removed from the system 1 and sent for further examination. Only after it has been established that there are no germs in the Petri dish opened during filling is the correspondingly filled batch of pharmaceuticals released.

15 As can be seen from Fig. 2 to 4, the device 3 for air monitoring comprises a vertical magazine 33 for this purpose, in which Petri dishes 30 can be stored one above the other. Next to the magazine 33 there is a so-called collecting head 34 of an air sampler, in which an opened Petri dish is placed in order to carry out the air monitoring. A measuring point 6 is thus
20 provided in the collecting head 34.

In addition to the collecting head 34, the device 3 for air monitoring also comprises an air outlet pipe 35, so that air flows from above into the collecting head 34 onto the opened Petri dish placed therein and is
25 released via the air outlet pipe 35.

The system 1 also comprises an identification device 9, for example a scanner or a camera, which is used to identify the particular Petri dish 30 which is currently being used for air monitoring. For this purpose, the Petri
30 dishes 30 have, for example, barcodes or identification numbers or the like in order to be reliably recognized by means of the identification device 9.

Depending on the length of the filling and sealing process, multiple Petri dishes 30 have to be used for air monitoring.

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For this purpose, the system 1 also comprises an automatic handling device 4, which in this embodiment is a 6-axis robot. The automatic

handling device 4 automatically carries out the microbiological air monitoring by means of the Petri dishes 30.

5 In the initial position shown in Fig. 2, exactly three Petri dishes 30 are arranged in the magazine 33 in this embodiment. In a first step, the automatic handling device 4, which comprises a gripper 40 having a first gripping jaw 41 and a second gripping jaw 42, is guided to the collecting head 34 and this is removed from the device 3 for air monitoring and placed at a storage location 5, which is arranged on the magazine 3. This state is shown in Fig. 3.

10 In a next step, the gripper 40 is guided to one of the Petri dishes 30 in the magazine 33 and one of the Petri dishes 30 is removed from the magazine. The removed Petri dish is placed on a measuring point 6 of the device 3 for air monitoring.

15 In a next step, the gripper 40 then removes the lid 31 from the Petri dish placed on the measuring point 6 and places the lid 31 in the magazine 33. This state is shown in Fig. 4.

20 In a next step, the gripper 40 then takes the collecting head 34 from the storage point 5 and positions it over the opened Petri dish 30 on the measuring point 6.

25 The measuring process can now begin in that the device 3 for air monitoring sucks in air from above through the collecting head 34 and releases it again via the air outlet pipe 35. If germs are present in the enclosed space 2, they are fed to the culture medium in the lower receptacle 31 of the opened Petri dish in the collecting head 34 and can be detected.

30 After a predetermined period of time, the Petri dish used for monitoring must be replaced with a new Petri dish. For this purpose, the automatic handling device 4 first removes the collecting head 34 again from the device 3 for air monitoring and places it at the storage location 5. The lid 31 stored in the magazine 33 is then removed from the magazine and placed on the lower receptacle 31 of the Petri dish on the measuring point

6. Then the Petri dish 30, which has been closed again in this way, is removed from the measuring point 6 and placed in the magazine 33.

5 If a further measurement is to be carried out, the automatic handling device 4 then removes the next unused Petri dish 30 from the magazine 33 and positions it again on the measuring point 6. The air monitoring sequence described above is then repeated.

10 The use of the magazine 33 also has the advantage that a large number of Petri dishes 30 can be brought into and out of the machine in one step, which further simplifies handling.

15 Thus, microbiological air monitoring can be carried out over an entire batch using multiple Petri dishes, and fully automatic handling is possible.

The automatic handling device 4 of this embodiment is also designed so that the containers are also fed from the filling station 10 to the sealing station 11. This process is carried out by the automatic handling device 4 in those time periods in which it is not necessary to change the Petri dish 30 for air monitoring. Thus, in addition to changing the Petri dishes, the automatic handling device 4 also has additional handling tasks, namely a task of transporting filled containers from the filling station 10 to the sealing station 11. It should be noted that the automatic handling device 4 can also take on other transport tasks, for example feeding empty containers to the filling station or removing sealed, filled containers from the sealing station to a storage position.

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35 Thus, according to the invention, microbiological air monitoring can be achieved with automatic Petri dish handling. This is reproducible and much more reliable compared to the manual handling processes in the prior art, as the risk of human intervention is not present in the invention. In the pharmaceutical sector in particular, this can avoid the risk of unwanted contamination, for example due to particles that can detach from gloves when they are moved through the glove port or due to clumsy Petri dish handling.

In particular, changing the Petri dishes 30 during the filling process cannot be forgotten, since this can be done automatically by a control device.

The identification device 9 can also be used to provide secure and traceable documentation of the samples in the Petri dishes 30.

5 It should also be noted that the gripper 40 of the robot can also be provided for example in an exchangeable manner, if certain format specifications of the containers would not allow gripping with the gripper for the Petri dishes. For this purpose, an automatic gripper changing device can be provided in the enclosed space 2.

10

PATENTKRAV

1. Anlæg til håndtering af følsomme produkter, især til fyldning og forsegling af medikamenter i beholdere, omfattende

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- et aflukket rum (2), hvor de følsomme produkter håndteres,
- en indretning (3) til overvågning af luften i det aflukkede rum (2) med et målepunkt (6) og i det mindste én petriskål (30), hvilken petriskål (30) omfatter en nedre modtageindretning (31) og et aftageligt låg (32), og

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- en automatisk håndteringsindretning (4),
- hvor den automatiske håndteringsindretning (4) er udformet til automatisk at transportere petriskålen til målepunktet (6) og tilbage og at fjerne låget (32) fra det nedre modtagerum (31) af petriskålen (30) og fører det tilbage derpå,

15 **kendetegnet ved, at**

den automatiske håndteringsindretning (4) er udformet til at udføre yderligere håndteringstrin, især transporttrin, for beholdere til modtagelse af produkterne.

2. Anlæg ifølge krav 1, hvor indretningen (3) til overvågning af luften omfatter en luftkimsamler med et samle hoved (34) og et magasin (33) til optagelse af adskillige petriskåle (30).

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3. Anlæg ifølge krav 2, hvor den automatiske håndteringsindretning (4) er indrettet til at aftage og påsætte samle hovedet (34) på luftkimsamleren.

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4. Anlæg ifølge ethvert af de foregående krav, som yderligere omfatter en fyldestation (10) til fyldning af de følsomme produkter i beholdere og en forseglingsstation (11) til forsegling af de fyldte beholdere.

30 5. Anlæg ifølge krav 4, hvor den automatiske håndteringsindretning er udformet til at transportere beholderne fra fyldestationen (10) til forseglingsstationen (11).

6. Anlæg ifølge ethvert af de foregående krav, hvor den automatiske håndteringsindretning (4) omfatter en robot, især en 6-akset-robot.

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7. Anlæg ifølge krav 6, hvor robotten omfatter en griber (40) med en første og anden gribekæbe (41, 42).

5 8. Anlæg ifølge ethvert af de foregående krav, som yderligere omfatter en identifikationsindretning (9), som er udformet til at identificere petriskåle (30) og at tildele en forudbestemt måletid til en identificeret petriskål (30).

10 9. Anlæg ifølge krav 8, hvor hver petriskål (30) har en individuel optisk identifikationsmarkering og identifikationsindretningen (9) har en optisk identifikationsindretning til at genkende identifikationsmarkeringen på petriskålen.

10. Anlæg ifølge ethvert af de foregående krav, hvor anlægget er et isolatoranlæg eller et RABS-anlæg.

Fig. 1

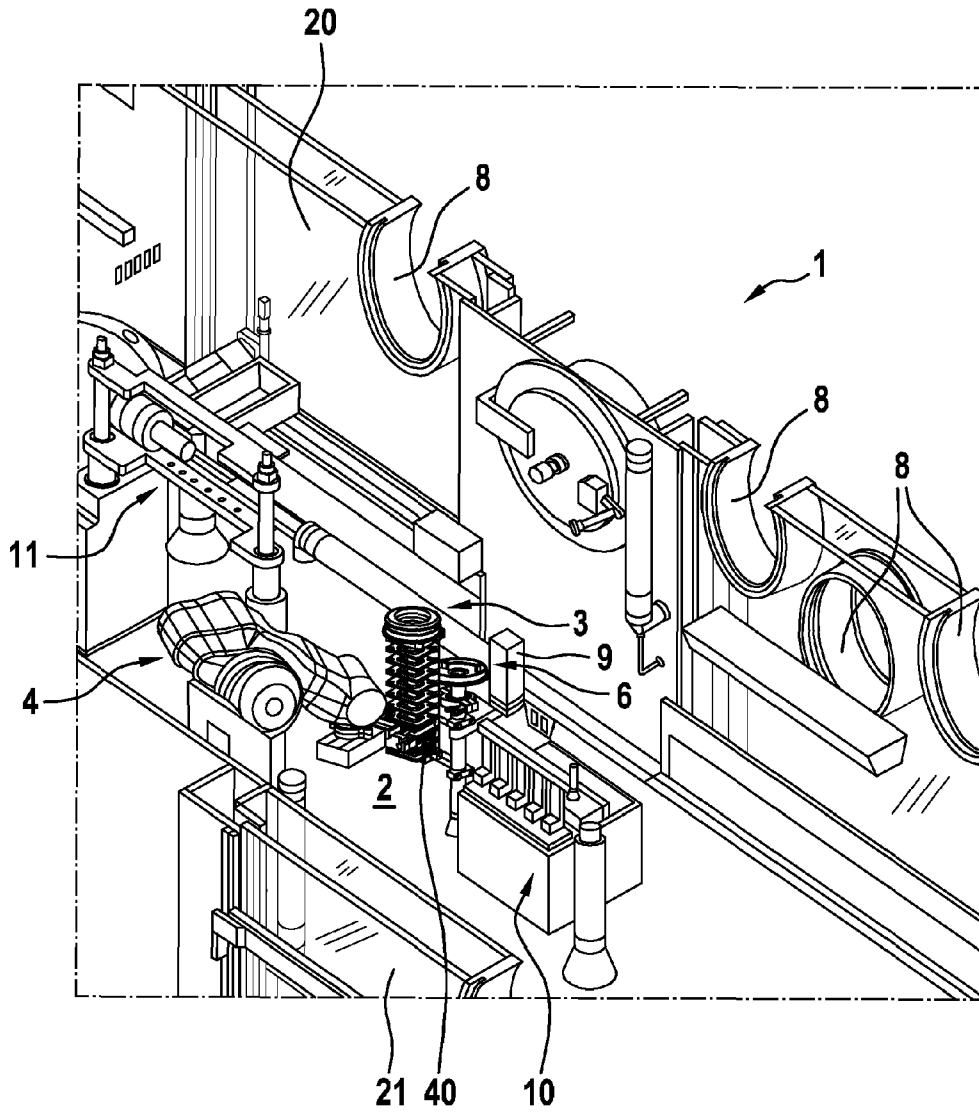


Fig. 2

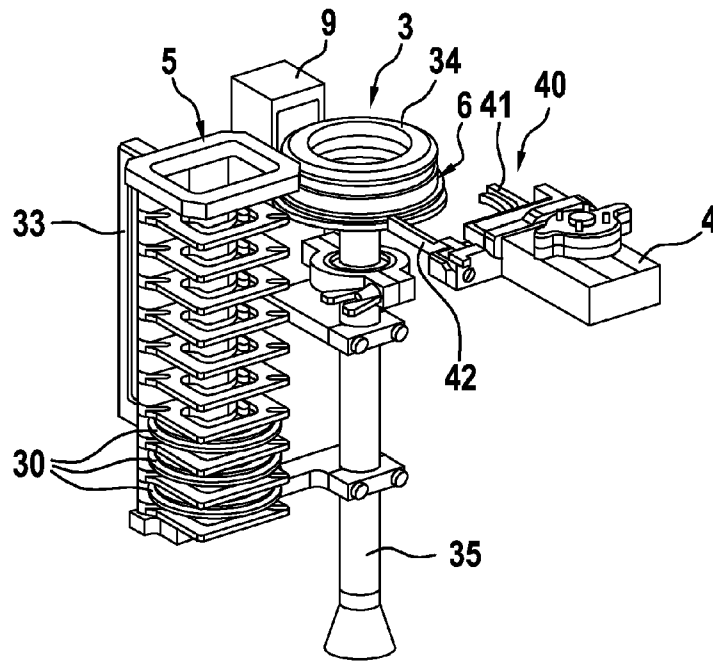


Fig. 3

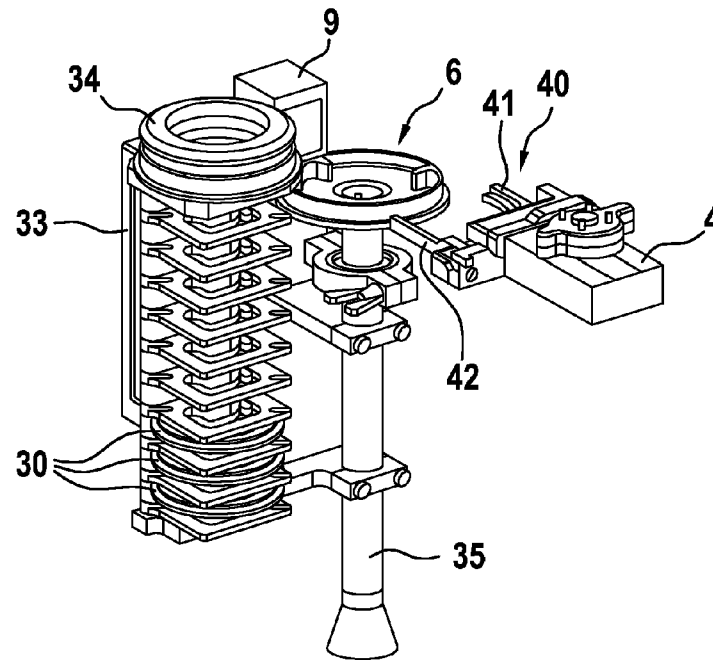


Fig. 4

