

EUROPEAN QUALIFYING EXAMINATION 2008

PAPER C

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Hagström, 01.03.2008

Dear Mr. MacAllpain

We are writing to you to ask you to file a notice of opposition against European Patent EP 1 702 008 B1 (Annex 1) on our behalf. We hope the documents included (Annexes 2-6) will be of use to you.

Annex 6 is an affidavit from Dr. Blackmore who is working on a book about sterilising agents. The affidavit confirms that a chapter of the book called "Guidelines for sterilisation" (see the affidavit) was handed out at a public conference well before the filing date of the opposed patent. Can we use the affidavit as evidence?

The patent proprietor has informed me that they will contest that the text mentioned in Annex 6 has been handed out by Dr. Blackmore at the above mentioned conference. We would like to offer Blackmore as a witness. Can the opposition division base a decision on Annex 6 without hearing Dr. Blackmore if the proprietor requests to have him heard?

Unfortunately Dr. Blackmore has a slight problem with both the German and Dutch authorities. He would thus prefer not to go to Germany or The Netherlands again. Would it still be possible to hear him as a witness?

The patent proprietor has also informed me that they intend to introduce further dependent claims based on the patent description if we file an opposition. Can they succeed?

We understand that the presentation of information is not patentable and instructions would seem to constitute a mere presentation of information. Does this invalidate claim 3?

Best regards,

Stephen Morse

Enclosures:

Annex 1

Annex 2

Annex 3

Annex 4

Annex 5

Annex 6

(19)



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European Patent Office
Office européen des brevets**

(11) **EP 1 702 008 B1**

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(54) **Concept for monitoring a sterilisation process**

Concept pour la surveillance d'un procédé de stérilisation

Konzept zur Überwachung eines Sterilisationsverfahrens

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Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European Patent Convention).

[0001] Many items such as medical instruments and cooking ware need thorough sterilisation in order to prevent the spread of diseases. Sterilisation can be carried out in a simple apparatus by means of heat. In hospitals sterilisation is usually performed using heat and a sterilising agent in the form of water vapour.

5

[0002] The present inventors have created an improved sterilising apparatus as defined in claim 1, which is provided with a window suitable for viewing any object placed within the apparatus during the entire sterilisation process. By means of the window the operator of the apparatus may continuously monitor if anything goes wrong within the apparatus.

10

[0003] It is generally advisable to place a sterilisation indicator within a sterilising apparatus for testing the extent of sterilisation. With the present apparatus, it is possible to monitor the extent of the sterilisation from the outside if such an indicator is placed visibly within the apparatus. Thereby it may be prevented that the apparatus is opened before the process has completed.

15

[0004] According to the invention the apparatus is capable of heating the object to be sterilised to at least 100 °C which is enough to kill most common germs. In order to provide a more efficient sterilisation, even higher temperatures, preferably at least 105 °C, may be used. A thermometer may be provided for monitoring the temperature.

20

[0005] Also a combination of means for different sterilising techniques may be applied. For instance we have found that a chemical sterilising agent may be applied in conjunction with heat to improve sterilisation. When using a chemical sterilising agent the apparatus should be air-tight to prevent contamination of the surroundings. Figure 1 shows a preferred embodiment of the apparatus (1) being hermetically sealable and being provided with a source of a chemical sterilising agent (7) having a valve (6) for controlling the supply of the agent into the apparatus.

25

[0006] In addition the object can be irradiated. Ultraviolet (UV) light is the preferred type of irradiation since it is easy to control. In order to protect the operator from the hazards of extended irradiation with UV-light, the window of the apparatus is preferably provided with a UV-light blocking coating allowing only visible light to pass through. The
5 combination of heat with both a chemical sterilising agent and UV-light provides particularly efficient sterilisation applicable to critical objects such as test-tubes.

[0007] The apparatus according to the invention can be used with the known indicators. However, these indicators are mechanical devices which deform when subjected to heat
10 or steam. This may cause the problem that they move out of sight during the sterilisation process.

[0008] The inventors have found that the apparatus according to the invention is preferably used in conjunction with an indicator in the form of a mark applied directly to
15 the object. This provides the additional advantage that it is evident from the object itself whether it has been sterilised even after it has left the apparatus.

[0009] Accordingly, the invention also concerns an aqueous ink for marking the object to be sterilised. The ink contains one or more compounds capable of changing colour
20 when subjected to a chemical sterilising agent such as hydrogen peroxide. Alternatively the ink can be made sensitive to other sterilising conditions such as UV-light or heat. Suitable compounds providing a clearly visible colour change are known in the art.

[0010] It is advantageous to provide instructions on how to use the ink. The instructions
25 may be in any form, for example they may be printed, or be in a machine readable format such as on a computer disc or they may be made available via the Internet.

[0011] The ink can be applied to self-adhesive labels in the form of machine readable codes. Particularly preferred are the so-called "smart-codes". These are matrix codes which encode data in two dimensions, i.e. with a plurality of rows and columns of data. Smart-codes are technically superior to the traditional linear bar codes as they encode
5 significantly more data per unit area and are much more resistant to data degradation due to a more sophisticated built-in error correction system. By employing a smart-code it is possible to encode several pieces of information with only one code, for instance information relating to the origin or nature of the product to be sterilised and instructions on how to handle the product. The self-adhesive label may be used to track the product.

10

[0012] Accordingly, an aspect of the invention concerns a self-adhesive label comprising at least one machine readable code capable of changing colour from white to black when subjected to a sterilising agent. A change from white to black gives a particularly strong contrast which is favourable for machine reading. The substance Alu-
15 W has proved to be particularly suitable for providing the desired colour change. Fig. 2 illustrates a smart-code printed with Alu-W.

[0013] The indicators of the invention can be used advantageously in a process for sterilisation of a test-tube as defined in claim 6. The process furthermore exploits the
20 synergistic effect of using heat, UV-light and a chemical sterilising agent to provide the highest degree of sterilisation.

[0014] Any chemical sterilising agent may be used. However, hydrogen peroxide is preferred because it decomposes into non-hazardous components. It is often required
25 that absolutely no hazardous residues are left after sterilisation.

[0015] The chemical sterilising agent should be in the gas phase. This ensures that it enters everywhere where contaminants are present. Accordingly vaporous hydrogen peroxide is particularly preferred as the sterilising agent.

Claims

1. Apparatus (1) for sterilising comprising a sterilising chamber with a door (2) and an electrical source of heat capable of raising the temperature in the chamber
5 and a means (3) for setting the desired temperature wherein a tray (5) for accepting an object to be sterilised is situated within the chamber and wherein said apparatus is provided with a window (4) for viewing the object on the tray while being sterilised.
- 10 2. An apparatus according to claim 1 further being hermetically sealable and comprising a source of a chemical sterilising agent (7) and control means (6) for controlling the supply of the agent into the chamber.
- 15 3. A product comprising: an aqueous ink capable of changing colour when subjected to a sterilising agent; and instructions for the use of the ink, said instructions defining the following steps : I) marking an object to be sterilised with the ink, II) exposing the object to a sterilising agent and III) inspecting the ink-mark to determine whether the sterilisation was successful.
- 20 4. Self-adhesive label comprising at least one machine readable code capable of changing colour from white to black when subjected to a chemical sterilising agent.
5. Label according to claim 4 wherein the machine readable code is a smart-code.

25

... / ...

6. Process for sterilising a test-tube, comprising the following steps:

- a) placing a sterilising indicator on the test-tube,
- b) simultaneously exposing the test-tube and the indicator to a temperature of at least 105 °C, to a chemical sterilising agent in the gas phase and to irradiation with UV-light,

wherein said indicator is capable of changing visual appearance when subjected either to the chemical sterilising agent or to the UV-light.

7. Sterilising process according to claim 6 wherein the chemical sterilising agent is hydrogen peroxide.

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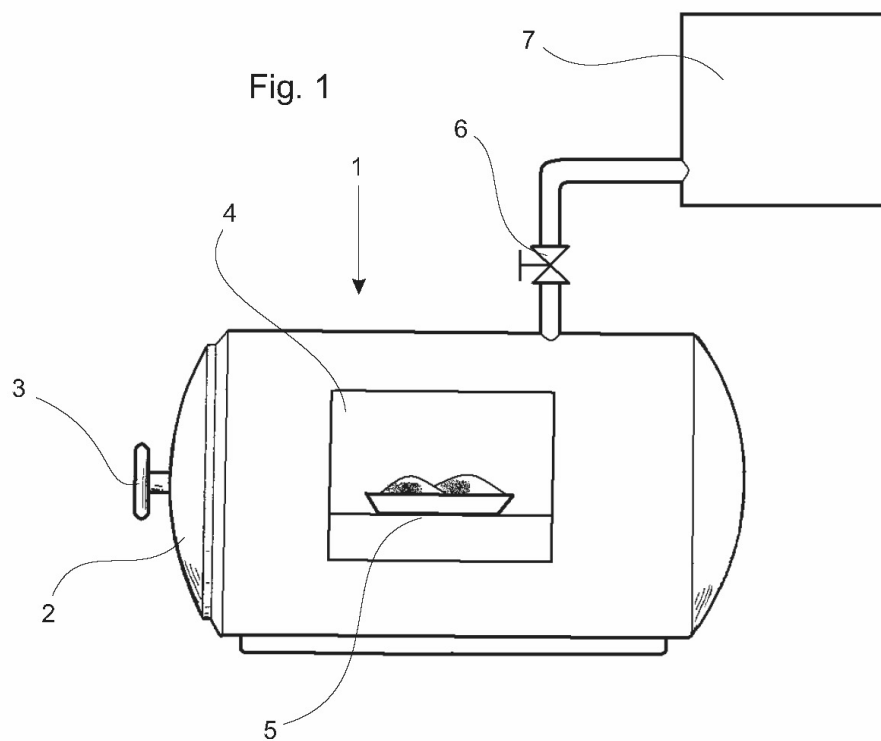
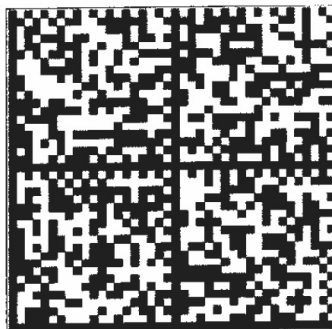


Fig. 2



Journal de Stérilisation ; Sthac Publications, 94880 Noisseau, France

Vol. 123, 2002

Pages 9-10

« Indicateurs de stérilisation : nouvelles tendances »

5 **Auteur : Y. Malmsteen**

Des systèmes indicateurs ont été développés récemment qui changent d'apparence sous l'effet de conditions stérilisantes. On peut donc munir des objets à stériliser d'une marque qui réagit aux conditions stérilisantes et indique si l'objet a bien été stérilisé.

10 Ceci facilite grandement le contrôle de qualité de la stérilisation et est beaucoup plus rapide et plus efficace que la technique consistant à contrôler un à un des objets sélectionnés de manière aléatoire.

15 Le choix de l'indicateur correct est cependant une opération délicate car il existe une multitude de méthodes de stérilisation différentes. Les informations rassemblées ici sous forme de guide visent à orienter ce choix, en fonction de la méthode de stérilisation. Les méthodes les plus courantes sont détaillées individuellement dans la section ci-dessous.

1. Stérilisation à la vapeur :

20

Les composés suivants se décomposent lors d'une stérilisation à la vapeur et produisent un changement de couleur prononcé.

	<u>Moyen de stérilisation</u>	<u>Indicateur</u>	<u>Couleur avant</u>	<u>Couleur après</u>
25	Vapeur	Thiosulfate de plomb	Blanc	Noir
		Thiosulfate de cuivre	Jaune	Noir

2. Stérilisation par la lumière ultraviolette (UV) :

30 Les substances suivantes peuvent être utilisées pour détecter une stérilisation aux UV.

	<u>Moyen de stérilisation</u>	<u>Indicateur</u>	<u>Couleur avant</u>	<u>Couleur après</u>
	UV	β -jaune	Rose clair	Jaune clair
		α -bleu	Jaune délavé	Bleu ciel

3. Stérilisation au moyen d'agents oxydants :

Les indicateurs ci-dessous sont adaptés pour oxyder les agents stérilisants oxydants tels que le peroxyde d'hydrogène.

5

<u>Moyen de stérilisation</u>	<u>Indicateur</u>	<u>Couleur avant</u>	<u>Couleur après</u>
Oxydant	Alu-R	Rouge	Blanc
	Alu-W	Blanc	Noir
	Alu-B	Noir	Blanc

10

4. Remarques finales :

Les indicateurs susmentionnés peuvent être élaborés sous forme d'encres, par exemple en les diluant dans de l'eau, et lesdites encres peuvent être apposées par impression ou écriture sur l'objet à stériliser. Ainsi, chaque objet contient l'information concernant sa stérilisation ou sa non-stérilisation.

15

Pour que l'opérateur du dispositif stérilisateur puisse suivre le déroulement de la stérilisation, il est conseillé de placer les objets munis d'un indicateur dans le dispositif stérilisateur de sorte que l'indicateur soit observable de l'extérieur, à travers un panneau transparent. Ceci est mieux adapté que de s'en remettre à un moyen indicateur placé sur le dispositif. Par ailleurs, un tel panneau permet à l'opérateur de s'assurer que tout est normal à l'intérieur du dispositif.

20

WO 85/000321

(19) Weltorganisation für geistiges Eigentum, Internationales Bureau

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(81) Bestimmungsstaaten: **AT, AU, CH, DE, DK, ES, FI, GB, IT,
JP, MX, NO, SE, US**

20 (54) Bezeichnung: **Nachverfolgungssystem**

[0001] In automatisierten mehrstufigen Verfahren zur serienmäßigen Behandlung mehrerer Gegenstände ist es wesentlich, in der Folge der Verfahrensschritte den aktuellen Zustand jedes einzelnen Gegenstands ständig zu verfolgen.

25 **[0002]** Eine Möglichkeit hierzu ist das Anbringen eines Aufklebers, d. h. eines Haftetiketts, mit einem Punkt unterschiedlicher Farbe für jeden Verfahrensschritt. Leider bietet diese Art der Kodierung nur einen begrenzten Informationsgehalt und ist möglicherweise nur schwer maschinenlesbar.

- [0003]** Ein anderer Ansatz bestand in der Anwendung sogenannter linearer Barcodes, die Daten als eindimensionale Anordnung von Balken und Abständen kodieren. Diese Codes haben den Vorteil, dass sie viel mehr Informationen enthalten können als ein farbiger Punkt, d. h. sie haben eine höhere Datendichte. Zum Beispiel kann jeder
5 einzelne zu bearbeitende Gegenstand mit einem einzigartigen Barcode versehen werden, durch den er eindeutig identifiziert werden kann. Darüber hinaus sind Barcodes gut maschinenlesbar und weniger anfällig für Datenbeschädigung, da fakultativ eine oder mehrere Prüfziffern aufgenommen werden können.
- 10 **[0004]** Dennoch bleibt das Problem bestehen, dass solche Aufkleber mit farbigen Punkten oder Barcodes zu dem Zeitpunkt auf dem Gegenstand angebracht werden sollten, an dem der betreffende Verfahrensschritt ausgeführt wird, was sich nicht immer gut bewerkstelligen lässt.
- 15 **[0005]** Die Erfinder haben nun die Idee entwickelt, Aufkleber mit Barcodes zu verwenden, die je nach Hintergrundfarbe in Reaktion auf vordefinierte Bedingungen sichtbar oder unsichtbar gemacht werden können. So kann der Aufkleber bereits vor jeder Behandlung auf dem Gegenstand angebracht werden, und die kodierten Informationen können bei Bedarf einfach (de)aktiviert werden.
- 20 **[0006]** Es ist bekannt, dass verschiedene chemische Stoffe unter bestimmten Bedingungen wie der Einwirkung von Dampf, UV-Strahlung oder Oxidation ihre Farbe ändern können. Die vorliegende Erfindung macht sich dieses Prinzip zunutze, indem auf einen Aufkleber eine geeignete Beschichtung aus einem Stoff aufgebracht wird, der die
25 Informationen sichtbar oder unsichtbar machen kann, wenn er den entsprechenden Bedingungen ausgesetzt wird.
- [0007]** Erfindungsgemäß kann ein beliebiger bekannter Stoff verwendet werden, der seine Farbe ändern kann. Bevorzugt werden Stoffe, die einen ausgeprägten Kontrast
30 zwischen den verschiedenen Farbstufen bieten, da dies die Maschinenlesbarkeit erleichtert. Vorzuziehen wären demnach Änderungen von Schwarz zu Weiß oder von Weiß zu Schwarz, wobei uns derzeit kein geeigneter Stoff bekannt ist, der die zuletzt genannte Änderung ermöglicht.

[0008] Neben der Verwendung in der industriellen Fertigung können die erfindungsgemäßen Aufkleber auch in vielen anderen Gebieten der Technik, einschließlich der Lebensmittelverarbeitung, sowie im Gesundheitswesen, z. B. in Krankenhäusern, zu jedem Nachverfolgungszweck eingesetzt werden.

5

Die Erfindung wird anhand folgender Figuren weiter veranschaulicht:

Fig. 1) "Punkt"-Indikator aus dem Stand der Technik

Fig. 2) Barcode gemäß einer Ausführungsform der Erfindung

10

Der in Fig. 2 dargestellte Barcode besteht aus der Substanz Alu-B und wird unter Einwirkung eines Oxidationsmittels weiß, d. h. unsichtbar.

15 **Anspruch:**

- 1) Aufkleber zu Nachverfolgungszwecken umfassend ein folienförmiges Substrat, das auf der einen Oberfläche mit einem Klebstoff und auf der gegenüberliegenden Oberfläche mit mindestens einem Barcode versehen ist, dadurch gekennzeichnet, dass wenigstens ein Barcode mit einer Substanz gedruckt ist, deren Farbe unter Einwirkung von Dampf, UV-Strahlung oder Oxidation veränderbar ist.

20

1/1

Fig. 1



Fig. 2



(19) United States

(12) Patent Publication, Hendrix et al.

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(43) Pub. Date: **Aug. 22, 1967**

5 (75) Inventors: **J. Hendrix, Fender County, MI, (US);
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(21) Appl. No.: **05/294,412**

10 (22) Filed: **Feb. 4, 1963**

(51) Int. Cl.: **A61L2/04**

(52) U.S. Cl.: **422/125**

Apparatus for sterilisation

15

[0001] The present invention is concerned with an apparatus for sterilisation using mainly dry heat. Additionally, the apparatus may be hermetically sealable and comprise a source of a chemical sterilising agent to allow for even more efficient sterilisation.

20

[0002] The apparatus comprises a thermally insulated chamber with a door and a burner or an electrical source of heat to raise the temperature within the chamber. Preferably the apparatus will have a temperature control knob to set the temperature and a detachable tray or basket within the chamber for receiving the object to be sterilised.

25

[0003] Unfortunately it is generally not possible to determine from an object itself whether it has been sterilised or not. For determining whether the goods in the apparatus have been sterilised, an indicator means can be placed within the apparatus. However, it will not allow the operator to determine from the outside if and when the
30 sterilisation conditions are reached. The present invention solves this problem by providing a sterilising apparatus with an integrated indicator means as defined in claim 1.

[0004] The preferred indicator means according to the invention is a thermometer which is fixed as an integral part of the apparatus, i.e. its walls or door, so it does not get lost. The thermometer is mounted with its sensor within the sterilising chamber and with its scale visibly placed immediately behind a small window exactly matching the size of
5 the scale.

Fig. 1 shows a conventional apparatus (1) with a door (2) having a handle (3) for opening the door.

Fig. 2 shows an apparatus according to the invention further comprising a temperature
10 control knob (4), a visible thermometer scale (5) and a source of a chemical sterilising agent (6) connected to the apparatus via a valve (7).

Claim:

15

- 1) Apparatus (1) for sterilisation comprising a chamber for receiving an object to be sterilised, a door (2) for sealing the apparatus during operation and a thermometer mounted as an integral part of the apparatus (1) with a sensor within the chamber and with a thermometer scale (5) being visible from the outside.

1/1

Fig. 1

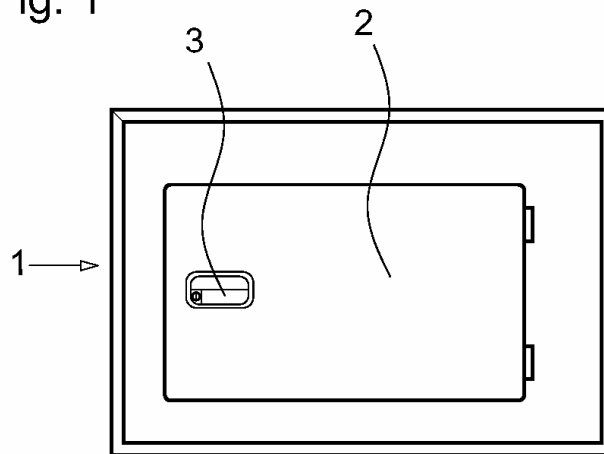
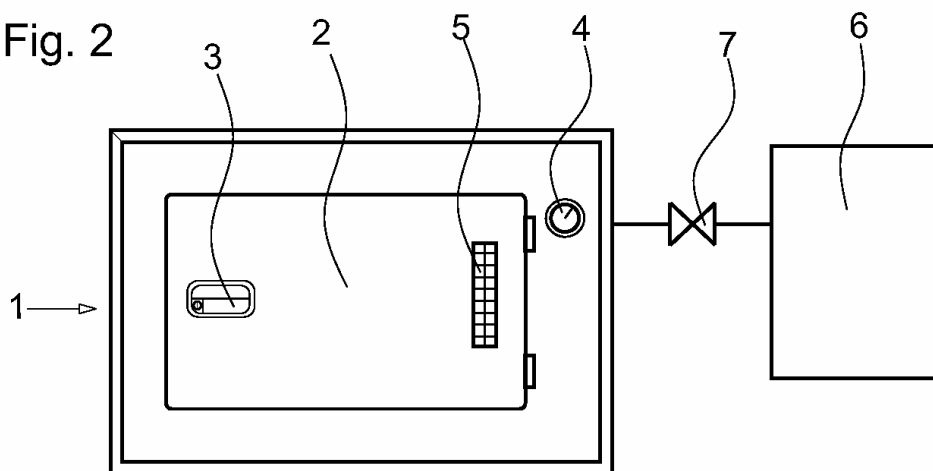


Fig. 2



(19) République Française, Institut National de la Propriété Industrielle, Paris

(11) N° de publication: **1 212 121**

(21) N° d'enregistrement national : **99 09090**

(51) Int Cl: **A61L2/04, A61L2/10, A61L2/18,**

5

A61L2/20, A61L2/24

(12) Demande de Brevet d'Invention A1

(22) Date de dépôt: **23.08.99**

(30) Priorité: **-**

(43) Date de mise à la disposition du

10

public de la demande: **28.02.2001 Bulletin 01/09**

(71) Demandeur(s): **Lag Sterilisation S.A.**

(72) Inventeurs(s): **Wylde, Z. et Satriani, J.**

(74) Mandataire(s): **Cabinet P. Rondat**

15 **Procédé pour stériliser des récipients**

[0001] La consommation de repas instantanés a beaucoup augmenté durant les dernières décennies. Les plats surgelés qui peuvent être réchauffés dans un four à micro-ondes ou un four normal sont très appréciés.

20

[0002] Si l'on veut que les repas instantanés se conservent longtemps, tout doit être mis en oeuvre pendant leur production pour éviter les contaminations et réduire le nombre de bactéries ambiantes. Par conséquent, il importe de stériliser également l'emballage qui est en contact avec les aliments. Les récipients utilisés pour emballer les repas instantanés sont souvent en matériau thermoplastique. Sous peine de faire fondre les récipients, ces derniers ne doivent en aucun cas être chauffés à des températures élevées, c'est-à-dire à des températures qui dépasseraient 120°C. Il y a donc des cas où une stérilisation purement thermique est exclue.

25

30 **[0003]** Pour obtenir une stérilisation suffisante des récipients à aliments, il est courant de les stériliser à température ambiante, en utilisant des agents stérilisants chimiques puissants tels que les hypohalogénites aqueux, lesquels nécessitent malheureusement une étape de nettoyage supplémentaire pour garantir l'élimination des résidus toxiques.

[0004] Afin de réduire la quantité d'hypohalogénites nécessaire à la stérilisation, les auteurs de la présente invention ont étudié l'utilisation conjointe d'hypohalogénites dilués et de lumière UV. Ils en ont conclu qu'une telle combinaison produisait une stérilisation suffisante, qui n'endommageait pas le récipient, et ne laissait subsister que des résidus infimes. La présente invention porte donc sur une méthode telle que définie à la revendication 1.

[0005] Il a été constaté de manière surprenante que la lumière UV augmente l'efficacité de n'importe quel agent stérilisant chimique. Cet effet est particulièrement prononcé quand l'agent stérilisant chimique est utilisé à l'état gazeux et à haute température.

[0006] Dans la mise en oeuvre du procédé de l'invention, le récipient (figure 1, référence 3) passe dans un tunnel de stérilisation (1). À l'intérieur du tunnel, en même temps qu'il passe sous une ou plusieurs lampes UV, le récipient est chauffé à une température adéquate - inférieure au point de fusion du matériau dont est constitué le récipient – par exposition à un agent stérilisant chimique chaud à l'état gazeux. L'exposition prolongée à la lumière UV étant nocive pour l'opérateur, le dispositif doit être rendu complètement opaque de sorte que l'opérateur soit dans l'impossibilité d'observer ce qui se passe à l'intérieur du dispositif. L'entrée et la sortie du dispositif sont masquées par des rideaux (2). Une extraction continue des gaz du tunnel permet de maintenir l'intérieur de ce dernier à une pression inférieure à la pression atmosphérique, afin d'empêcher que l'agent stérilisant chimique gazeux ne s'échappe du dispositif.

[0007] La réussite de la stérilisation est vérifiée sur des récipients sélectionnés aléatoirement à leur sortie du dispositif. Chaque récipient stérilisé sera préférentiellement muni d'une date et d'un numéro de lot, par exemple au moyen d'un code-barres.

[0008] On peut encore augmenter la durée de conservation en décontaminant la surface supérieure des aliments par pulvérisation de peroxyde d'hydrogène liquide sur leur surface réfrigérée, juste avant de fermer le récipient à aliments.

[0009] Compte tenu de son fort effet stérilisant, la méthode selon l'invention convient aussi au traitement d'objets pour lesquels la stérilisation est particulièrement critique, comme par exemple les éprouvettes et les cathéters.

5 La figure 1 montre un dispositif (1) utilisé selon l'invention.

La figure 2 montre un plateau typique (7) contenant une préparation de restauration rapide vue à travers la porte de verre (6) d'un four électrique classique réglé (5) à 120°C (4).

10

Revendications :

1. Méthode pour stériliser un récipient constitué d'une matière thermoplastique, en chauffant le récipient à une température allant de 100 à 120°C, et en l'exposant
15 simultanément à un agent stérilisant chimique gazeux et à de la lumière UV.
2. Méthode selon la revendication 1, où le récipient est un plateau à aliments ou une éprouvette.

1/1

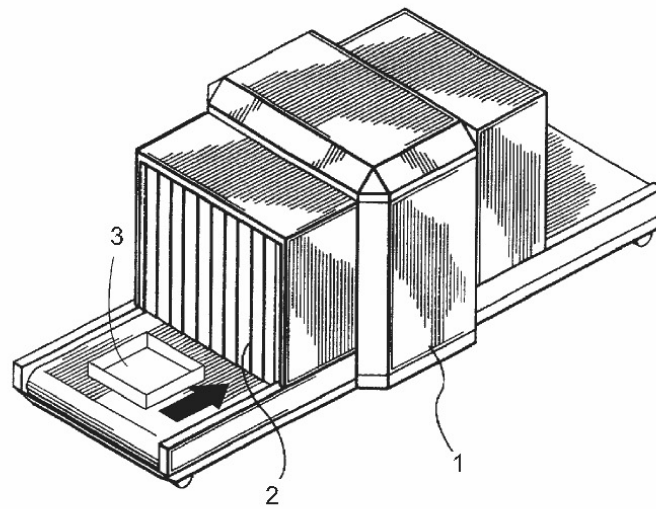


Fig. 1

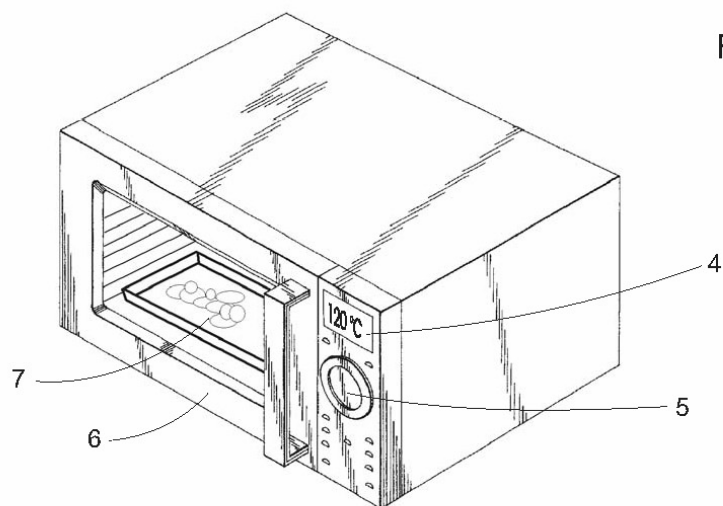


Fig. 2

Affidavit:

I Dr. Richard Blackmore, 1 S. White Street, Glasgow G63 9RH, Great Britain, hereby declare that the text below was handed out to members of the public prior to 13.02.2003.

5

Glasgow, 22.01.08,

R Blackmore

Dr. Richard Blackmore

10 **Guidelines for sterilisation:**

In recent years there has been a tendency to use more environmentally friendly chemical agents for cleaning and sterilising objects. An example of such an agent is hydrogen peroxide, which decomposes to components which are not harmful to human
15 beings.

In order to ensure sufficient sterilisation, various attempts have been made to increase the effectiveness of these environmentally friendly chemical agents.

20 Generally combining the use of a chemical agent with other sterilising means e.g. heat, steam (i.e. water vapour at 100 °C) or electromagnetic radiation will provide a synergistic effect.

In addition it has been found that using chemical sterilising agents in the gas phase
25 rather than in the liquid phase will improve their antimicrobial effect even further. Surprisingly hydrogen peroxide in the gas phase has proved to be just as efficient for sterilisation as gaseous hypohalogenite, which is known to leave toxic residues.

The effect of gas-phase sterilisation can even be further enhanced in combination with
30 other means such as heat and/or irradiation.

In order to ensure maximum safety it is advisable to pack chemical sterilising agents with instructions for use and mark the packages by normal text, Braille and a machine readable code. The latter could be in the form of a conventional linear barcode which encodes data in one dimension. It would be even better to employ a two-dimensional
5 data matrix barcode, also known as a “smart-code”. This type of code is nowadays commonly used as postal stamps or for providing tracking information on parcels. These codes have the technical advantage of having a much higher data density and they can be machine decoded successfully even if a large part of the image has been damaged.

ÜBERSETZUNG DER ANLAGEN 2 BIS 6

Anlage 2:	in Englisch
Anlage 3:	in Englisch
Anlage 4:	in Französisch
Anlage 5:	in Deutsch
Anlage 6:	in Deutsch

TRANSLATION OF ANNEXES 2 TO 6

Annex 2:	into English
Annex 3:	into English
Annex 4:	into French
Annex 5:	into German
Annex 6:	into German

TRADUCTION DES ANNEXES 2 À 6

Annexe 2 :	en anglais
Annexe 3 :	en anglais
Annexe 4 :	en français
Annexe 5 :	en allemand
Annexe 6 :	en allemand

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Pages 9-10

Sterilisation indicators: New trends

5 **Author : Y. Malmsteen**

Recently indicator systems have been developed which change appearance when subjected to sterilising conditions. Accordingly, it has become possible to provide individual items to be sterilised with a mark which reacts to the sterilising conditions and indicates whether the item has been sterilised or not. This greatly facilitates quality control of the sterilising process, i.e. it is much faster and more efficient than testing randomly picked items separately.

To apply the correct indicator is, however, a challenging task because a great number of quite different sterilisation methods exist. This information has been collected as a guide for selecting the correct indicator material depending on the sterilisation method chosen. Each of the most common methods will be dealt with in the individual sections below:

1. Steam sterilisation:

The following compounds will decompose under steam sterilisation conditions and produce a pronounced colour change:

<u>Sterilising means</u>	<u>Indicator</u>	<u>Colour before</u>	<u>Colour after</u>
Steam	Lead thiosulphate	White	Black
	Copper thiosulphate	Yellow	Black

2. Sterilisation using UV-Light:

In order to detect sterilisation with UV-light the following substances could be used:

<u>Sterilising means</u>	<u>Indicator</u>	<u>Colour before</u>	<u>Colour after</u>
UV-Light	β -yellow	Light pink	Light yellow
	α -blue	Faded yellow	Sky blue

3. Sterilisation using oxidising agents:

Indicators below are suitable for oxidising sterilising agents such as hydrogen peroxide.

5	<u>Sterilising means</u>	<u>Indicator</u>	<u>Colour before</u>	<u>Colour after</u>
	Oxidant	Alu-R	Red	White
		Alu-W	White	Black
		Alu-B	Black	White

10 4. Final remarks:

The above-mentioned indicator materials can be formulated as inks e.g. by diluting with water and said inks can be applied through printing or writing onto the item to be sterilised. Thereby each individual item itself contains the information about whether it
15 has been sterilised or not.

To allow the operator of the sterilising apparatus to monitor the process, it is advisable to place the items provided with an indicator within the sterilising apparatus, so that the indicator can be seen from the outside through a transparent panel. This is better than
20 relying only on any indicating means placed on the apparatus. Moreover, such panel allows the operator to see if anything goes wrong within the apparatus.

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(81) Designated States: **AT, AU, CH, DE, DK, ES, FI, GB, IT,**

JP, MX, NO, SE, US

20 (54) Title: **Tracking system**

[0001] In automated multi-step processes for treating multiple items in series, it is essential to keep track of the current state of each item in the sequence of process

25 steps.

[0002] One way of doing this is to apply a sticker, i.e. self-adhesive label, with a differently coloured dot for each process step. Unfortunately such coding provides only a limited amount of information and can be difficult for machines to read.

[0003] Another approach has been to employ so-called linear barcodes which encode data in a one-dimensional array of bars and spaces. These codes have the advantage that they can contain much more information than a coloured dot, i.e. they have a higher data density. For instance each individual item to be processed can be provided with a
5 unique barcode allowing for unambiguous identification thereof. Furthermore, barcodes are easily machine-readable and they are less sensitive to data degradation due to the optional inclusion of one or more check-digits.

[0004] Nevertheless, a problem remains that such stickers with coloured dots or
10 barcodes should be applied on the item at the point of the process where the step in question is carried out, which is not always convenient.

[0005] The present inventors have now come up with the idea of using stickers with barcodes which depending on the background colour can be caused to appear or
15 disappear in response to pre-selected conditions. In this way a sticker can be placed on the item before any treatment and the encoded information can simply be (de-)activated when needed.

[0006] It is known that various chemical substances are capable of changing colour
20 when subjected to specific conditions such as steam, UV-radiation or oxidation. The present invention makes use of this principle by providing a sticker with a suitable coating with such a substance allowing the information to appear or disappear by exposing it to the appropriate conditions.

[0007] For the purpose of this invention any known substance, capable of changing
25 colour, may be used. Preferred substances provide a pronounced contrast between the various colour stages as this will facilitate machine reading. Preferred changes would thus be black to white or white to black, but we are presently not aware of any suitable substance which enables the latter change.

[0008] Apart from the use in industrial manufacturing, the stickers of the present invention may be used for any tracking purposes in many other technical fields including food processing and in the health sector such as in hospitals.

5 The invention will now be illustrated further by means of figures:

Fig. 1) Prior art "dot" indicator,

Fig. 2) Barcode according to an embodiment of the invention

10 The barcode in fig. 2 is composed of the substance Alu-B and will turn white, i.e. disappear, when treated with an oxidizing agent.

Claim:

15

- 1) A sticker for tracking purposes comprising a sheet-formed substrate provided with a glue on one surface and one or more barcodes on the opposite surface, characterized in that at least one barcode is printed with a material capable of changing its colour when subjected to steam, UV-radiation or oxidation

20

treatment.

1/1

Fig. 1



Fig. 2



(19) Etats-Unis

(12) Publication de Brevet, Hendrix et al.

(10) Numéro de publication : **3,030,303 B1**

(43) Date de publication : **Aug. 22, 1967**

5 (75) Inventeurs : **J. Hendrix, Fender County, MI, (US);
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(73) Cessionnaire : **Heritage Rock Research Inc.;
Kalamazoo, MI 49007, USA**

(21) Numéro de dépôt : **05/294,412**

10 (22) Date de dépôt : **Feb. 4, 1963**

(51) Int. Cl.: **A61L2/04**

(52) U.S. Cl.: **422/125**

Dispositif de stérilisation

15

[0001] La présente invention porte sur un dispositif de stérilisation utilisant principalement la chaleur sèche. Le dispositif peut, en outre, être fermé hermétiquement, et comprendre une source d'agent stérilisant chimique qui rend la stérilisation encore plus efficace.

20

[0002] Le dispositif comprend une chambre isolée thermiquement, avec une porte ainsi qu'un brûleur ou un source électrique de chaleur pour élever la température à l'intérieur de la chambre. Le dispositif sera préférentiellement équipé d'un bouton de contrôle servant à régler la température, et d'un plateau amovible ou réceptacle à l'intérieur de la

25 chambre pour recevoir les objets à stériliser.

25

[0003] Malheureusement, l'objet lui-même ne permet généralement pas de savoir s'il a ou non été stérilisé. Pour déterminer si les produits placés dans le dispositif ont été stérilisés, on peut placer un indicateur à l'intérieur du dispositif. Ceci ne permettra

30 cependant pas à l'opérateur de déterminer, de l'extérieur, si et à quel moment les conditions de stérilisation ont été réalisées. La présente invention résout ce problème grâce à son dispositif stérilisateur doté d'un indicateur intégré, tel que défini à la revendication 1.

30

[0004] L'indicateur préféré de l'invention est un thermomètre fixe intégré au dispositif, plus précisément à ses parois ou à sa porte, de sorte qu'il ne puisse pas se perdre. Le thermomètre est monté, avec son capteur, dans la chambre de stérilisation, son échelle étant positionnée de manière visible juste derrière une petite fenêtre dont les
5 dimensions coïncident exactement avec celles de l'échelle.

La figure 1 montre un dispositif classique (1) avec sa porte (2) dotée d'une poignée (3) servant à ouvrir la porte.

La figure 2 montre le dispositif de l'invention qui comprend, en plus, un bouton de
10 contrôle de la température (4), une échelle thermométrique visible (5) et une source d'agent stérilisant chimique (6) reliée au dispositif via une valve (7).

Revendication :

15

- 1) Dispositif de stérilisation (1) comprenant une chambre pour recevoir un objet à stériliser, une porte (2) pour fermer hermétiquement le dispositif pendant son fonctionnement, ainsi qu'un thermomètre intégré au dispositif (1) avec un capteur à l'intérieur de la chambre et une échelle thermométrique (5) visible de l'extérieur.

1/1

Fig. 1

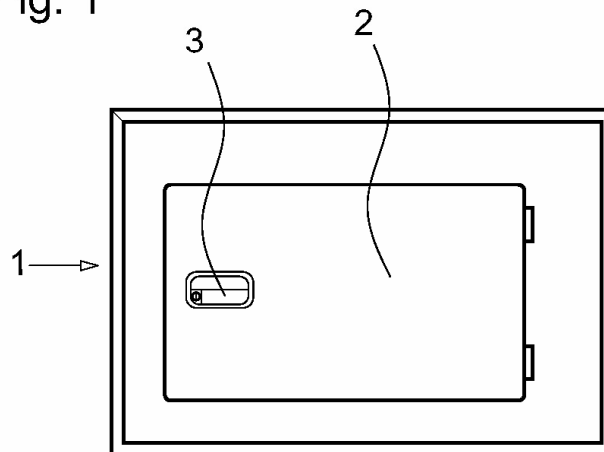
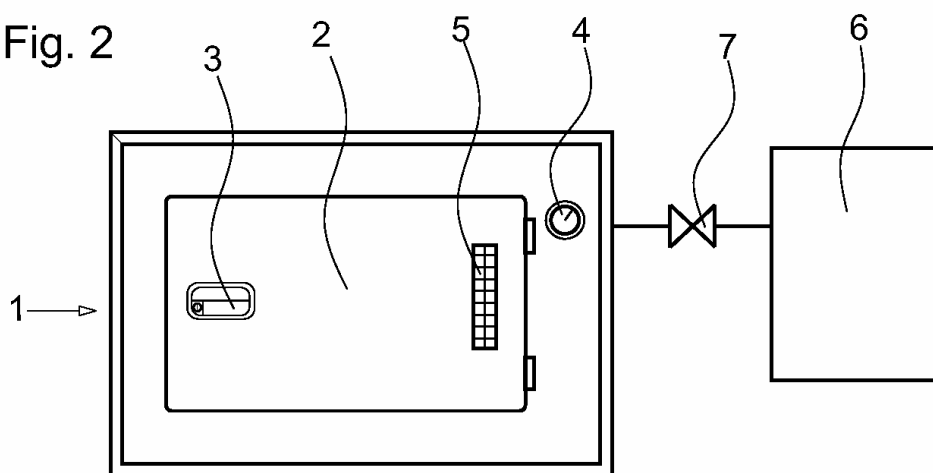


Fig. 2



Frankreich, Institut für geistiges Eigentum, Paris

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(51) Internationale Patentklassifikation: **A61L2/04, A61L2/10, A61L2/18,**
A61L2/20, A61L2/24

Patentanmeldung

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(30) Priorität: **-**
(43) Veröffentlichungstag: **28.02.2001 Patentblatt 01/09**
(71) Anmelder: **Lag Sterilisation S.A.**
(72) Erfinder: **Wylde, Z. et Satriani, J.**
(74) Vertreter: **Cabinet P. Rondat**

Verfahren zur Sterilisation von Behältern

[0001] In den letzten Jahrzehnten hat der Verzehr von Fertiggerichten beträchtlich zugenommen. Tiefkühlgerichte, die in der Mikrowelle oder in einem normalen Backofen aufgewärmt werden können, sind sehr beliebt.

[0002] Damit Fertiggerichte lange lagerfähig sind, muss während der Herstellung jede Verunreinigung unterbunden und die Zahl der natürlich vorkommenden Bakterien verringert werden. Dementsprechend sollte auch das Verpackungsmaterial, das mit den Lebensmitteln in Kontakt kommt, sterilisiert werden. Behälter, die zur Verpackung von Fertiggerichten verwendet werden, bestehen oft aus thermoplastischem Material. Damit die Behälter nicht schmelzen, ist darauf zu achten, dass sie nicht auf hohe Temperaturen erhitzt werden, d. h. nicht über 120 °C. Daher ist eine rein thermische Sterilisation nicht immer möglich.

[0003] Um eine ausreichende Sterilisation zu gewährleisten, ist es üblich, dass Lebensmittelbehälter bei Zimmertemperatur mit starken chemischen Sterilisationsmitteln wie wässrigen Hypohalogeniten sterilisiert werden, die leider einen zusätzlichen Reinigungsschritt erforderlich machen, damit die Entfernung giftiger Rückstände gewährleistet werden kann.

[0004] Um die Menge der für die Sterilisation benötigten Hypohalogenite verringern zu können, haben die Erfinder die kombinierte Anwendung von verdünntem Hypohalogenit und UV-Licht untersucht. Sie sind zu dem Ergebnis gekommen, dass diese tatsächlich eine ausreichende Sterilisation leisten kann, die den Behälter nicht beschädigt und nur
5 minimale Rückstandsspuren hinterlässt. Dementsprechend bezieht sich die vorliegende Erfindung auf ein Verfahren gemäß Anspruch 1.

[0005] Überraschenderweise wurde festgestellt, dass UV-Licht die Wirksamkeit eines beliebigen chemischen Sterilisationsmittels erhöht. Diese Wirkung ist besonders
10 ausgeprägt, wenn die chemischen Sterilisationsmittel im gasförmigen Zustand und bei hohen Temperaturen verwendet werden.

[0006] Zur Durchführung des erfindungsgemäßen Verfahrens bewegt sich der Behälter (Fig. 1, Nr. 3) durch einen Sterilisationstunnel (1). Im Tunnel wird der Behälter durch
15 Einwirkung eines heißen gasförmigen chemischen Sterilisationsmittels auf eine geeignete Temperatur unterhalb des Schmelzpunktes des Behältermaterials erhitzt und gleichzeitig unter einer oder mehreren UV-Lampen durchgeführt. Da eine längere Einwirkung von UV-Licht schädlich für das bedienende Personal ist, muss die Vorrichtung unbedingt vollständig undurchsichtig sein, sodass das bedienende Personal
20 nicht in die Vorrichtung hineinsehen kann. Ein- und Ausgang der Vorrichtung sind mit Vorhängen (2) verdeckt. Durch kontinuierliches Absaugen von Gas aus dem Tunnel wird das Innere des Tunnels auf einem Druck unterhalb des Atmosphärendrucks gehalten, damit das gasförmige chemische Sterilisationsmittel nicht aus der Vorrichtung
25 entweichen kann.

[0007] Der Erfolg der Sterilisation wird an zufällig ausgewählten Behältern überprüft nachdem diese die Vorrichtung verlassen haben. Es ist bevorzugt, jeden sterilisierten Behälter mit einem Datum und einer Chargennummer zu kennzeichnen, z. B. mit Hilfe eines Barcodes.

[0008] Zur zusätzlichen Optimierung der Lagerfähigkeit kann die Oberfläche der Lebensmittel selbst dekontaminiert werden, indem unmittelbar vor dem Verschließen des Lebensmittelbehälters flüssiges Wasserstoffperoxid auf die abgekühlte Lebensmitteloberfläche gesprüht wird.

[0009] Aufgrund seiner starken sterilisierenden Wirkung eignet sich das erfindungsgemäße Verfahren auch für die Behandlung von Gegenständen, deren Sterilisation besonders kritisch ist, wie zum Beispiel Reagenzgläsern und Kathetern.

- 5 Fig. 1 zeigt eine erfindungsgemäß eingesetzte Vorrichtung (1).
Fig. 2 zeigt eine übliche Aufnahmeplatte (7) enthaltend eine Fast-Food-Zubereitung gesehen durch die Glastür (6) eines herkömmlichen Elektroofens, der auf 120 °C (4) eingestellt (5) wurde.

10

Ansprüche:

15

1. Verfahren zum Sterilisieren eines Behälters aus thermoplastischem Material durch Erhitzen des Behälters auf eine Temperatur zwischen 100 °C und 120 °C, wobei der Behälter gleichzeitig einem gasförmigen chemischen Sterilisationsmittel und UV-Licht ausgesetzt wird.
2. Verfahren gemäß Anspruch 1, wobei der Behälter ein Lebensmittelbehälter oder ein Reagenzglas ist.

1/1

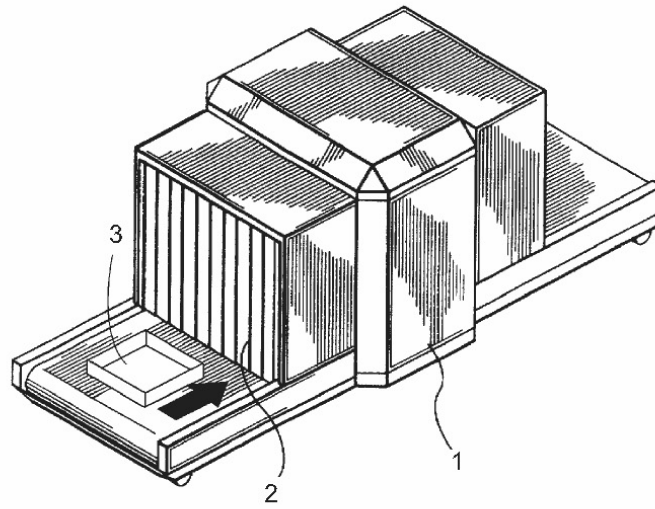


Fig. 1

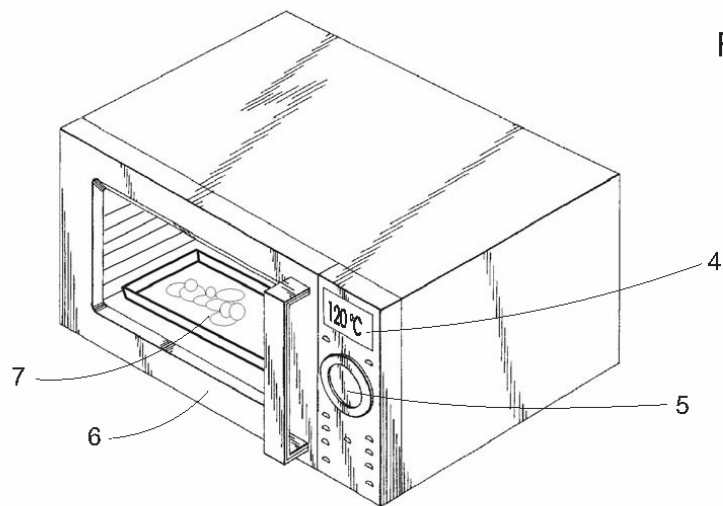


Fig. 2

Eidesstattliche Erklärung:

Ich, Dr. Richard Blackmore, 1 S. White Street, Glasgow G63 9RH, Großbritannien,
erkläre hiermit, dass der nachstehende Text vor dem 13.02.03 an Mitglieder der
5 Öffentlichkeit ausgehändigt worden ist.

Glasgow, 22.01.08, *R Blackmore*
Dr. Richard Blackmore

10 **Richtlinien für die Sterilisation:**

In den vergangenen Jahren gab es die Tendenz, bei der Reinigung und Sterilisation von
Gegenständen umweltfreundlichere chemische Mittel einzusetzen. Ein Beispiel für ein
solches Mittel ist Wasserstoffperoxid, das sich in für den Menschen unschädliche
15 Bestandteile zersetzt.

Damit eine ausreichende Sterilisation gewährleistet werden kann, wurde wiederholt
versucht, die Wirksamkeit dieser umweltfreundlichen chemischen Mittel zu erhöhen.

20 Im allgemeinen bewirkt das Kombinieren der Verwendung eines chemischen Mittels mit
anderen Sterilisationshilfsmittel wie Hitze, Dampf (d. h. Wasserdampf bei 100 °C) oder
elektromagnetischer Strahlung einen Synergieeffekt.

Darüber hinaus wurde festgestellt, dass sich bei chemischen Sterilisationsmitteln die
25 antimikrobielle Wirkung noch weiter verstärkt, wenn sie im gasförmigen statt im flüssigen
Zustand verwendet werden. Überraschenderweise wurde bei Wasserstoffperoxid im
gasförmigen Zustand eine genauso gute sterilisierende Wirkung festgestellt wie bei
gasförmigem Hypohalogenit, das bekanntermaßen giftige Rückstände hinterlässt.

30 Die Wirkung der Gasphasen-Sterilisation kann in Kombination mit anderen Hilfsmitteln,
wie z. B. Hitze und/oder Bestrahlung, sogar noch weiter erhöht werden.

Damit höchste Sicherheit gewährleistet werden kann, ist es ratsam, chemische Sterilisationsmittel zusammen mit einer Anleitung für den Gebrauch zu verpacken und die Verpackung mit normalem Text, mit Braille-Schrift und mit einem maschinenlesbaren Code zu kennzeichnen. Letzterer könnte ein herkömmlicher linearer Barcode sein, der
5 Daten eindimensional kodiert. Es wäre noch besser, einen zweidimensionalen Datenmatrix-Barcode zu verwenden, der auch unter der Bezeichnung "Smartcode" bekannt ist. Ein solcher Code wird heute häufig als Poststempel verwendet oder dient der Bereitstellung von Informationen zur Nachverfolgung von Paketen. Diese Codes haben den technischen Vorteil, dass sie eine viel höher Datendichte haben und dass sie
10 auch dann noch gut maschinenlesbar sind, wenn große Bereiche des Bilds beschädigt worden sind.

ÜBERSETZUNGSHILFE / GLOSSARY / GLOSSAIRE

DE	EN	FR	IT	SE	ES	NL
Brief des Einsprechenden / Opponent's Letter / Lettre de l'opposant						
Anleitung	instructions	instructions	istruzioni	bruksanvisning /anvisning	instrucciones	instructies
Anlage 1 / Annex 1 / Annexe 1						
Aufnahmeplatte	tray	plateau	vassoio	upptagningsbricka	bandeja	dienblad, bakje
Ventil	valve	valve	valvola	ventil	válvula	ventiel
Aussetzen	expose	exposer	sottoporre	utsätta	exponer	blootstellen
Verunreinigungen	contaminants	contaminations	agenti contaminanti	föreningar	impureza	verontreinigingen
hermetisch	hermetical	hermetiquement	ermeticamente	hermetisk	hermético	luchtdicht
luftdicht	air tight	étanche a l'air	stagno all'aria	lufttät	hermético	hermetisch
wässrig	aqueous	aqueuse	acquoso	vattenhaltig	acuosa	waterig
zersetzen	decompose	décomposer	decomporsi	upplösa / sönderdela	descomponer	ontbinden
Indikator	indicator	indicateur	indicatore	indikator	indicador	indicator
Nachverfolgung	tracking	traçabilité	tracciabilità	spårning	seguimiento	traceerbaarheid
Hilfsmittel	means	moyens	mezzo	hjälpmedel	medios	middel

ÜBERSETZUNGSHILFE / GLOSSARY / GLOSSAIRE

DE	EN	FR	IT	SE	ES	NL
Anlage 2 / Annex 2 / Annexe 2						
Indikator	indicator	indicateur	indicatore	indikator	indicador	indicator
zufällig	randomly	aléatoire	in modo casuale	slumpartat	aleatorio	toevallig
Anlage 3 / Annex 3 / Annexe 3						
Nachverfolgung	tracking	traçabilité	tracciabilità	spårning	seguimiento	traceerbaarheid
Datenbeschädigung	data degradation	dégradation des données	degradazione dei dati	försämring / degradering av data	degradación de datos	beschadiging van gegevens
Anlage 4 / Annex 4 / Annexe 4						
hermetisch	hermetical	hermétique	ermeticamente	lufttät	hermético	hermetisch
Ventil	valve	valve	valvola	ventil	válvula	ventiel
integriert	integrated	intégré	integrato	integrerad	integrado	geïntegreerd
Anlage 5 / Annex 5 / Annexe 5						
zufällig	randomly	aléatoire	in modo casuale	slumpartat	aleatorio	random/toevallig
giftig	toxic	toxique	tossico	giftig	tóxico	giftig
Elektroofen	electrical oven	four électrique	forno elettrico	elektrisk ugn	horno eléctrico	elektrische oven
Anlage 6 / Annex 6 / Annexe 6						
Sterilisationshilfsmittel	sterilisation means	moyens de stérilisation	mezzo di sterilizzazione	steriliseringsmedel	medios de esterilización	sterilisatiemiddel
Nachverfolgung	tracking	traçabilité	tracciabilità	spårning	seguimiento	traceerbaarheid

ÜBERSETZUNGSHILFE / GLOSSARY / GLOSSAIRE

DE	EN	FR	DK	FI	PT	BG
Brief des Einsprechenden / Opponent's Letter / Lettre de l'opposant						
Anleitung	instructions	instructions	vejledning	ohjeet	instrução	инструкция
Anlage 1 / Annex 1 / Annexe 1						
Aufnahmeplatte	tray	plateau	plade	pelti	tabuleiro	приемна плоча
Ventil	valve	valve	ventil	venttiili	válvula	клапан
Aussetzen	expose	exposer	udsætte for	sattaa alttiiksi	expôr	подлагане
Verunreinigungen	contaminants	contaminations	forurening	lika/saasteet	contaminantes	замърсявания
hermetisch	hermetical	hermetiquement	hermetisk	ilmatiivis	hermético	херметичен
luftdicht	air tight	étanche a l'air	lufttæt	ilmatiivis	hermético	въздухонепроницаем
wässrig	aqueous	aqueuse	vandbaseret	vesipitoinen	aguado	воден
zersetzen	decompose	décompose	nedbryde	hajottaa	decompôr	разлагам
Indikator	indicator	indicateur	indikator	indikaattori	indicador	индикатор
Nachverfolgung	tracking	traçabilité	eftersøgning/sporing	jäljitys	seguimento	следене
Hilfsmittel	means	moyens	middel	välineet/keinot	meio auxiliar	помощно средство

ÜBERSETZUNGSHILFE / GLOSSARY / GLOSSAIRE

DE	EN	FR	DK	FI	PT	BG
Anlage 2 / Annex 2 / Annexe 2						
Indikator	indicator	indicateur	indikator	indikaattori	indicador	индикатор
zufällig	randomly	aléatoire	tilfældigt	satunnainen	aleatório	случаен
Anlage 3 / Annex 3 / Annexe 3						
Nachverfolgung	tracking	traçabilité	eftersøge/spore	jäljitys	seguimento	следене
Datenbeschädigung	data degradation	dégradation des données	beskadigelse af data	tietojen vaurioituminen	danificação dos dados	повреждане на данните
Anlage 4 / Annex 4 / Annexe 4						
hermetisch	hermetical	hermétiquement	hermetisk	ilmativis	hermético	херметичен
Ventil	valve	valve	ventil	venttiili	válvula	клапан
integriert	integrated	intégré	integreret	integraitu	integrado	интегриран
Anlage 5 / Annex 5 / Annexe 5						
zufällig	randomly	aléatoire	tilfældigt	satunnainen	aleatório	случаен
giftig	toxic	toxique	giftig	myrkyllinen	tóxico	токсичен
Elektroofen	electrical oven	four électrique	elektrisk ovn	sähköuuni	forno eléctrico	електропещ
Anlage 6 / Annex 6 / Annexe 6						
Sterilisationshilfsmittel	sterilisation means	moyens de stérilisation	sterilisationsmiddel	sterilointi välineet	meios de esterilização	средство за стерилизация
Nachverfolgung	tracking	traçabilité	eftersøge/spore	jäljitys	seguimento	следене

Notes to the notice of opposition (EPO Form 2300)

Although the opposition form is not mandatory for the purpose of filing a notice of opposition, it specifies all the information required for such a notice to be admissible and hence facilitates the formulation and processing of the opposition. In stating and explaining the grounds for opposition, the opponent is free to comment as he wishes.

Explanatory notes to the various sections:

I. Patent opposed

Under **Patent No.** the number of the European patent against which opposition is filed (Rule 76(2)(b) EPC) must be given.

If known, the **application number and the date on which the Patent Bulletin mentions the grant** (Art. 97(3) EPC) should also be given. The latter makes it easier to monitor compliance with the opposition period.

The **title of the invention** must be given (Rule 76(2)(b) EPC); it should be indicated **as shown on the cover page of the printed patent specification** under item 54.

II. Proprietor of the patent

Where there are **several** patent proprietors, it is sufficient for the proprietor first named in the patent specification (under item 74) to be given.

III. Opponent

The **name, address and nationality** of the opponent and the **state** in which his residence or principal place of business is located must be given, in accordance with Rule 41(2)(c) EPC (Rule 76(2)(a) EPC). If the identity of the opponent has not been established by expiry of the opposition period, such deficiency can no longer be remedied (decision of the Technical Board of Appeal T 25/85, OJ EPO 1986, 81).

IV. Authorisation

If the opponent has appointed a **representative**, his name and the address of his place of business must be given, in accordance with Rule 41(2)(c) EPC (Rule 76(2)(d) EPC). If **several** professional representatives are appointed, only one representative to whom notification is to be made should be named. Any further representatives must be named in an annex (please put a cross in the appropriate box). In the case of an association of representatives, only the name and address of the association must be entered (see Rule 143(1)(h)).

An opponent who has neither a residence nor his principal place of business within the territory of one

of the EPC contracting states must be represented and act through his representative (Art. 133(2) EPC). Professional representation before the EPO may only be undertaken by professional representatives (Art. 134(1) EPC) or legal practitioners entitled to act as professional representatives (Art. 134(8) EPC).

Natural or legal persons having their residence or principal place of business within the territory of one of the EPC Contracting States may also be represented in opposition proceedings by an **employee**, who must, however, be authorised (Art. 133(3), first sentence, EPC). In this case notification will be made to the opponent (not the employee) unless a professional representative has also been authorised.

To avoid delaying the proceedings, any authorisation which has to be filed should if possible be enclosed with the opposition. Under Rule 152(1) EPC in conjunction with the decision of the President of the EPO dated 12 July 2007, listed professional representatives identifying themselves as such normally no longer need to file signed authorisations (cf. Special edition No. 3, OJ EPO 2007, L.1.). These are, however, required from legal practitioners and employees who are not professional representatives and are acting for the opponent under Articles 134(8) and 133(3), first sentence, EPC respectively. If they do not file an authorisation, the EPO will ask them to do so within a specified period. Failure to comply will result in any procedural steps performed by the practitioner or employee being deemed not to have been taken (Rule 152(6) EPC) – which means that the notice of opposition will be considered not to have been filed.

V. Statement of the extent to which the patent is opposed

The notice of opposition must contain a statement of the extent to which the European patent is opposed (Rule 76(2)(c) EPC). If the opposition is not filed against the patent as a whole (place a cross in the appropriate box), the number(s) of the claims (as in the patent specification) which the opponent considers to be affected by one or more of the grounds for opposition must be given.

VI. Grounds for opposition

The alleged grounds for opposition (Art. 100 EPC) must be indicated by a cross in the appropriate box(es).

Under the heading of non-patentability (Art. 100(a) EPC) the most frequently cited grounds for opposition are lack of novelty and lack of inventive step, for which separate boxes are provided. The form

otherwise gives the opponent ample scope for indicating other possible grounds for opposition. Under the heading “other grounds” the following Articles may be cited in the box provided: 52(1) and 57; 52(2); 53(a); 53(b); 53(c) EPC.

A full list of grounds for opposition is given in Article 100 EPC. The following in particular are not admissible grounds: lack of unity of invention (Art. 82 EPC), lack of clarity in the claims (Art. 84 EPC) and prior national rights (Art. 139(2) EPC).

For general information on grounds for opposition see Guidelines for Examination in the EPO, D-III, 5.

VII. Facts and arguments presented in support of the opposition

The notice of opposition must contain an indication of the facts and evidence presented in support of the opposition (Rule 76(2)(c) EPC) and, where documents are cited, an indication of the relevant part(s) (Guidelines D-IV, 1.2.2.1).

The facts, with the relevant arguments and evidence, in support of the opposition must be presented on a separate sheet enclosed as an annex to the Form (indicated by a pre-printed cross in the box).

The fact that the evidence is listed separately in Section IX does not anticipate the presentation of facts, evidence and arguments but merely makes for greater clarity and simplifies processing of the dossier. Section IX of the Form (Evidence presented) may of course always be referred to in this presentation.

Where documents are cited in shortened form, the rules set out in the Guidelines B-X, 9.1 should be followed.

VIII. Other requests

This section may be used for example to request oral proceedings or a file inspection.

IX. Evidence

Published documents cited as evidence (e.g. patent specifications) must be entered under “Publications” in the spaces provided – preferably in order of importance. They should be cited in the manner described in Guidelines B-X, 9.1.

Opponents should also indicate the parts of the document on which the opposition is based (this information has to be given anyway in the statement of facts and arguments – see notes to Section VII above).

Other evidence (e.g. witnesses, affidavits, company brochures, test or expert reports) must be cited under “Other evidence” (for public prior use: place, time, nature – see Guidelines D-V, 3.1.2; D-IV, 1.2.2.1(v); for witnesses: first name and last name, full address, relationship to opponent, etc.). If there is not enough

room, the evidence can simply be listed, with an indication of where in the statement of grounds the relevant particulars appear (e.g. “Witness ..., page 5”).

Documents cited by a party to opposition proceedings must be filed (including publications already cited in the European patent specification) with the notice of opposition or other written submission. This will avoid an invitation from the EPO for subsequent filing thereof. If they are neither enclosed nor filed in due time on invitation, the EPO may ignore any arguments based on them (Rule 83 EPC).

X. Payment of opposition fee

The opposition fee must be paid within the opposition period. Notice of opposition is not deemed to have been filed until the opposition fee has been paid (Art. 99(1) EPC). With regard to what constitutes the date to be considered as the date on which payment is made, see Article 7 of the Rules relating to Fees and the guidance on payment methods in the Official Journal.

XI. List of documents enclosed

Please indicate which documents are enclosed by crossing the relevant box.

XII. Signature

If the opponent is a legal person and the notice of opposition is not signed by the representative, it must be signed:

- (a) either by a person entitled to sign under the law or the opponent’s statute, articles of association or the like, with an **indication of the capacity of the person doing so**, e.g. Geschäftsführer, Prokurist, Handlungsbevollmächtigter; chairman, director, company secretary; directeur, fondé de pouvoir (Art. 133(1) EPC), in which case no authorisation need be filed;
- (b) or by another employee of the opponent, provided the latter’s principal place of business is in a contracting state (Art. 133(3), first sentence; Rule 152(1) EPC), in which case an authorisation must be filed.

Notice of opposition to a European patent

I. Patent opposed

Patent No.

Application No.

Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)

Title of the invention

II. Proprietor of the patent

first named in the patent specification

Opponent's or representative's reference
(max. 15 keystrokes)

III. Opponent

Name

Address

State of residence or of principal place of business

Nationality

Telephone/Fax

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Multiple opponents
(see additional sheet)

☐

IV. Authorisation

1. Representative

(name only one representative or name of association of representatives to whom notification is to be made)

Address of place of business

Telephone/Fax

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Additional representative(s)
on additional sheet/see authorisation

☐

Opponent's reference

2. Name(s) of employee(s) of the opponent authorised to act in these opposition proceedings under Art. 133(3) EPC

Authorisation(s) to 1./2. ☐ not considered necessary

☐ has/have been registered under No.

☐ is/are enclosed

V. Opposition is filed against

• the patent as a whole

☐

• claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

• it is not new (Art. 52(1); Art. 54 EPC)

☐

• it does not involve an inventive step (Art. 52(1); Art. 56 EPC)

☐

• patentability is excluded on other grounds, i.e. Article

☐

Art.

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC).

☐

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC).

☐

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith on a separate sheet (annex 1)

☒

VIII. Other requests:

Opponent's reference

IX. Evidence presented

Evidence is enclosed ☐
will be filed at a later date ☐

A. Publications:

1	
Particular relevance (page, column, line, fig.):	
2	
Particular relevance (page, column, line, fig.):	
3	
Particular relevance (page, column, line, fig.):	
4	
Particular relevance (page, column, line, fig.):	
5	
Particular relevance (page, column, line, fig.):	
6	
Particular relevance (page, column, line, fig.):	

Continued on additional sheet ☐

B. Other evidence

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Continued on additional sheet ☐

Opponent's reference

X. Payment of the opposition fee is made

- as indicated in the enclosed voucher for payment of fees and costs (EPO Form 1010) ☐
- via EPO Online Services ☐

XI. List of documents

Enclosure No.

- | | | |
|---|---|-------------------------------------|
| 0 | Form for notice of opposition | ☒ |
| 1 | Facts (see VII.) | ☒ |
| 2 | Copies of documents presented as evidence (see IX.) | |
| a | Publications | ☐ |
| b | Other documents | ☐ |
| 3 | Signed authorisation(s) (see IV.) | ☐ |
| 4 | Voucher for payment of fees and costs (see X.) | ☐ |
| 5 | Additional sheet(s) | ☐ |
| 6 | Other | ☐ |

Number
of sheets

Please specify here:

XII. Signature of opponent or representative

Place

Date

Signature

Name (block capitals)

In case of legal persons, signatory's position
within company

Opponent's reference