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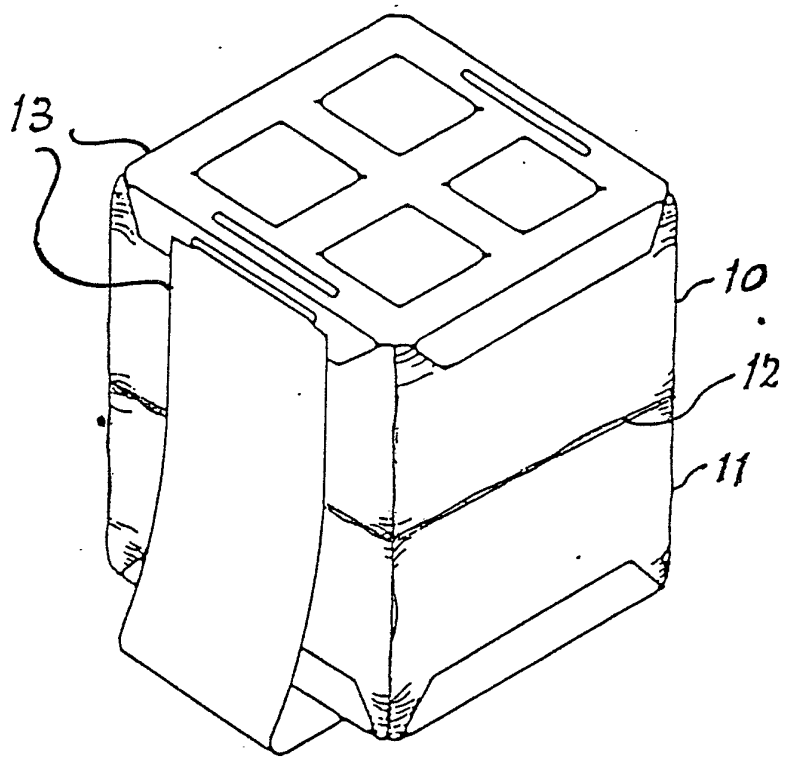

(57) Abstract

An indicator sheet for an autoclave test pack wherein a pair of porous masses (10) are held in close superimposed relationship by means of a clamp (13) with the indicator sheet (12) sandwiched between them. The indicator sheet (12) has printed thereon a pattern of markings (14) formed from one or more substances which are adapted under steam sterilizing conditions to provide an indication of the presence of air and/or excessive moisture such that each is evident and individually identifiable.

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AN INDICATOR SHEET FOR AN AUTOCLAVE TEST PACK

THIS INVENTION concerns a device for testing the efficiency of autoclaves such as those used in hospitals for sterilizing porous loads, and for detecting the presence of air in such a system, and is particularly concerned with an indicator sheet for use in such a device, which provides a visual indication of the presence of air and/or other substances under steam sterilizing conditions.

Porous loads are sterilized by subjecting them to saturated steam at a temperature of between 134°C and 138°C for a period of not less than 3 minutes. In order to ensure correct sterilizing conditions, the steam must penetrate unhindered to all parts of the load. This can be achieved only if all of the air is first removed from the sterilizer vessel and from its load, which is accomplished typically by a process of evacuation and steam flushing of the sterilizing vessel and its load.

Failure to remove all of the air or the subsequent leakage of air into an evacuated chamber, or the introduction of air or other gases in the steam supply, can cause gas pockets to remain within the porous load, usually in the inner regions thereof. In this case, the temperature within some parts of the load might be lower

than that required during all or part of the sterilizing process. Many types of testing device are known for this purpose including the so-called Bowie Dick towel test utilising a pack of linen Huckaback towels measuring some 270mm high and about 300mm x 200mm in plan. Another known system utilises sheets of porous paper or card, and in all of these cases it is necessary for an indicator to be placed in the centre of the stack so that after the test the indicator may be inspected to detect any parts thereof where air might have been present.

The test pack is processed in the sterilizer and the satisfactory result would show an even change in appearance across the whole of the indicator sheet, whereas the presence of air in the stack is indicated by a failure of the indicator to change its appearance in certain areas, usually at the centre. The test must be carried out daily before the sterilizer is used for the production of sterile porous loads.

Such indicators conventionally may consist of so-called autoclave tape which is placed across a sheet of paper, and reacts visibly to the presence of air and moisture under steam sterilizing conditions. Alternatively, there are available certain manufactured sheets having an indicator pattern printed thereon from a substance which, again, reacts by changing its appearance under steam sterilizing conditions.

It has been found that these conventional types of indicator suffer from the disadvantage that their appearance is affected by the presence of excessive moisture during the test, and this can lead to a false reading when attempting to detect the presence of air. In some cases, this can have the effect of a substance from the tape or sheet being transferred onto the material of the pack which in turn further affects the appearance of the indicator producing still further misleading results.

One kind of device for detecting the presence of air in a steam sterilizer has been proposed and comprises a first porous mass of at least substantially man-made material, a second porous mass of a similar material, an indicator adapted to undergo a visual change under moist heat sterilizing conditions and sandwiched between the masses thus to be in intimate contact therewith, and means for removably holding the masses and indicator in close superimposed relationship, said means being permeable to allow the free passage of air and steam to the external surfaces of the porous masses.

In this kind of device where a man-made material such as polypropylene is used in place of linen or paper, the presence of excessive moisture in the applied steam is particularly detrimental since none of the moisture can be

absorbed by the pack. As a result, the affect of the moisture on the indicator is more pronounced, and it is an object of the present invention to provide an improved indicator for use, particularly though not exclusively, with an autoclave test pack incorporating man-made materials.

According to the present invention there is provided an indicator sheet for an autoclave test pack, having across a substantial part of at least one of its surfaces, a pattern of indicator markings comprising at least one substance adapted to provide an indicatation of the presence of air and/or excessive moisture under steam sterilizing conditions such that, under such conditions, the presence of air and/or excessive moisture becomes evident and individually identifiable.

The invention will be further apparent from the following description, given by way of example only, with reference to the accompanying drawings in which:-

Fig. 1 is a perspective view of a device made in accordance with the invention;

and Fig 2 is an exploded view of some of the constituent parts thereof.

Referring now to the drawings, one form of device

for detecting the presence of air in a steam sterilizer comprises first and second porous masses 10 and 11 each formed from a stack of single sheets of a man-made woven or non-woven material such as spun bonded polypropylene having a weight in the region of 50 - 150 (and typically in the region of 100) grams per square metre. Each mass contains an appropriate number (typically between 60 and 300) of such sheets arranged in close superimposed relationship. Sandwiched between the masses 10 and 11 is an indicator sheet 12 bearing indicator markings 14 adapted to undergo a visual change during a test.

The markings 14 are such that after a test has been carried out to detect the presence of air under steam sterilizing conditions, there will be a clear indication on the sheet of the presence of air and/or excessive entrained moisture in the applied steam. Since excessive moisture can produce a false reading, perhaps suggesting to the operator the presence of air when no air is present, it is necessary to detect the presence of droplets of entrained moisture in the otherwise saturated steam, and for this to be visible on the indicator sheet as distinct from any indication of the presence of air. Thus in accordance with the invention the pattern of indicator markings printed or otherwise placed on backing sheet 12 is arranged to cover substantially the whole surface area of at least one face of the sheet and consists of at least one substance which

is capable of providing separately identifiable indications of the presence of air and excessive moisture.

A cover sheet 12a of a porous and absorbent material such as paper may be interposed between each face of sheet 12 and the adjacent surface of the mass 10 or 11. This may take the form of unglazed paper (bond) of weight typically 80g per square metre.

As can be seen in Fig. 1, the masses 10 and 11, and indicator 12 are placed in close superimposed relationship into a closable box or clamp 13 as a close fit therewithin. When closed the clamp applies a slight compressive force to its contents to ensure that they are firmly held together. The clamp may be of stainless steel or plastics, and allows free access of air and steam to the test pack. The pack is constructed in a manner which permits use for a number of successive tests, for example, up to 30 but preferably 10-15.

As can be seen from the drawing, in this embodiment, the pack when assembled is approximately cuboid and it has a side dimension typically in the region of 5 - 30 cm and preferably about 15 cm to allow for a reduction in height through compression during use.

The material from which the masses 10 and 11 are produced shall not give rise to exothermic reactions when

hydrated and must exhibit air/steam penetration characteristics similar to those of Huckaback towels which comply with British Standard BS 1781.

Experimental work has demonstrated that the device as described is capable of detecting the presence of air in a sterilizer. It is also clear from temperature measurements made within the device that the presence of air leads to a depression of temperature at the centre of the test pack similar to that observed with the Huckaback towel pack used in the conventional Bowie/Dick test.

In one example of sheet 12, the markings 14 are formed from a printed substance which may consist of a single substance which changes colour or other aspects of its appearance in the presence or absence of air.

In another example there may be two substances printed or otherwise placed on one surface of the sheet, or again, one on each surface, which change their appearances differentially, one being sensitive to excessive moisture and the other to air.

In another example, there may be a single substance whose appearance will change in the presence of air but will not change in the presence of excessive moisture when no air is present.

A substance which changes its appearance under steam sterilizing conditions is lead carbonate ink which converts to lead oxide and turns from light to dark in the absence of air. If pockets of air are present then these are indicated by zones where the substance has not changed or only partially changed its appearance. This substance, in the presence of excessive moisture under steam sterilizing conditions, will also tend to be solubilised and will thus transfer from the surface of the indicator sheet to the next adjacent surface such as a cover sheet 12a in the example given. Sheet 12a is preferably of an absorbant material such as paper.

In conventional cases where no moisture detection is called for, any tendency for the substance to transfer from one sheet to another can be prevented by coating of the lead carbonate ink with a moisture-impervious substance such as varnish. Thus protected, it is insoluble.

In one specific example as illustrated the sheet 12 has a pattern of radial lines projecting from a central position towards the edges. Each line may be between 0.25 cm and 2 cm in width and printed using a lead carbonate ink. The lines may be of uniform thickness or tapering towards the centre.

Certain selected and appropriately indicated ones of these lines can be protected against transfer in the presence of excessive moisture whilst others are left unprotected. This may be by pre-encapsulation or after-coating of the ink using a moisture-impervious, for example, polymeric substance.

The shape and arrangement of the lines or other markings across the surface of the sheet is to some extent arbitrary but should extend substantially across the entire surface so that when subjected to steam sterilizing conditions in a test pack of the kind described above the presence of air would be visible as areas where the ink is unchanged or only partially changed, whilst the presence of excessive moisture would be visible by way of transfer of the unprotected markings in those areas when excessive moisture is present.

Conveniently the sheet may be some 30 cm by 12 - 15 cm and folded to be approximately square with a side dimension in the region of 12 - 15 cm so that it can be placed in the test pack with two opposed marked surfaces.

The base sheet upon which the markings are printed is preferably of a porous material such as paper, and in use this may be placed in the pack with cover sheets of similar material super-imposed on both marked surfaces as

illustrated.

For certain applications the marked indicator sheet is preferably enclosed within an envelope of porous material such as spun bonded polypropylene or cellulosic material such as cotton or similar fabrics, or compressed paper or board-like material. In this way, the indicator sheet can be packaged and remain substantially unexposed prior to use.

Substances other than lead carbonate ink may be used provided that they are capable of indicating the presence of air and/or excessive moisture under steam sterilizing conditions.

In some case it is advantageous to use two different substances which give visual indications, for example, by change to different colours. One example might be amino acid compositions containing an indicator which changesfrom yellow to blue in the absence of air but from yellow to brown in the presence of air. Markings of such a material may be applied to the sheet in conjunction with one or more other materials indicating the presence of excessive moisture.

By providing an indicator sheet which will perform as described above under steam sterilizing conditions, a more positive and clearly identifiable result can be

obtained during an autoclave test so that it can be carried out by lesser skilled personnel not trained to recognise, without difficulty, the difference between an indicator affected by the presence of air, and one affected by excessive moisture, with or without the presence of air.

In an alternative form of test pack, incorporating an indicator sheet in accordance with the invention, the porous masses, when assembled, may be other than cuboid presenting, for example, a flatter rectangular pack some 4 cm in height with side dimensions in the regions of 30 cm and 20 cm respectively.

CLAIMS

1. An indicator sheet for an autoclave test pack having across a substantial part of at least one of its surfaces, a pattern of indicator markings comprising at least one substance adapted to provide an indication of the presence of air and/or excessive moisture under steam sterilizing conditions such that, under such conditions, the presence of air and/or excessive moisture becomes evident and individually identifiable.

2. An indicator sheet according to Claim 1, in which the markings are formed from a single substance printed or otherwise placed on said surface, which provides an indication of the presence of air under steam sterilizing conditions, and which is at least partially transferred to an adjacent superimposed sheet in the test pack in the presence of excessive moisture.

3. An indicator sheet according to Claim 1, in which the markings are formed from two substances printed or otherwise placed on said surface, which provide different indications one being sensitive to excessive moisture and the other to air.

4. An indicator sheet according to Claim 1, wherein

said markings are formed from a single substance whose appearance will change in the presence of air but will not change in the presence of excessive moisture when no air is present.

5. An indicator sheet according to Claim 1 or Claim 2, wherein the substance is lead carbonate ink, the pattern including some markings where the ink is protected such that it cannot be solubilised whilst other areas are unprotected such that they become solubilised in the presence of excessive moisture and are transferred onto an adjacent surface.

6. An indicator sheet according to Claim 5, wherein the protected markings are of pre-encapsulated ink.

7. An indicator sheet according to Claim 5, wherein the protected markings are of ink coated after application to the sheet.

8. An indicator sheet according to Claim 5, wherein the protected markings are pre-encapsulated or after-coated with a polymeric material.

9. An indicator sheet according to Claim 3, wherein at least one of said substances is an amino acid composition containing an indicator.

10. An indicator sheet according to any preceding claim, when included within an autoclave test pack comprising a first porous mass of at least substantially man-made material, a second porous mass of a similar material, the indicator sheet being sandwiched between the masses thus to be in intimate contact therewith, and means for removably holding the masses and indicator sheet in close superimposed relationship, said means being permeable to allow free passage of air and steam to the external surfaces of the porous masses.

11. An indicator sheet when included in an autoclave test pack according to Claim 10, wherein each said porous mass is formed from a stack of single sheets of a man-made woven or non-woven material such as spun bonded polypropylene having a weight in the region of 50 - 150 grammes per square metre.

12. An indicator sheet included in an autoclave test pack according to Claim 10, wherein said means for removably holding the masses and indicator sheet enclosed superimposed relationship is formed as a clamp enclosing its contents and applying a slight compressive force thereto to ensure that they are held firmly together.

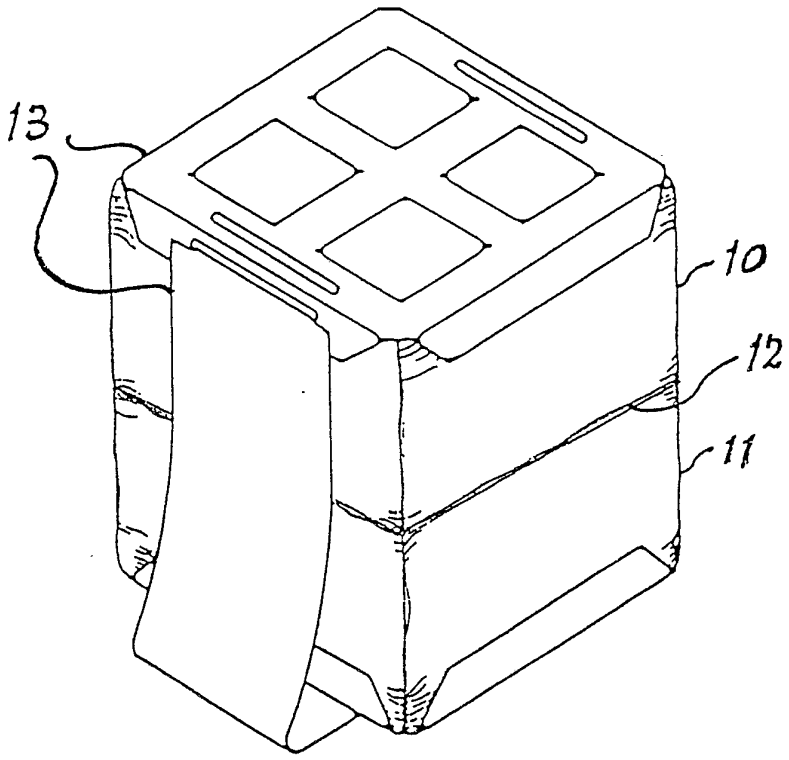

FIG.1

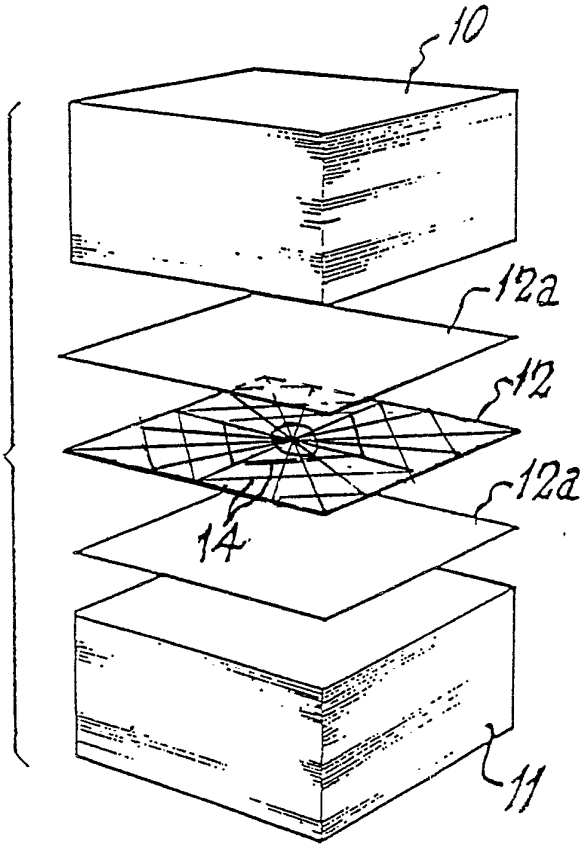

FIG.2

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00125

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 L 2/26

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 L; G 01 N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	GB, A, 1458553 (DICKINSON) 15 December 1976 see claims 1,3,13	1,2,5
X	GB, A, 2143322 (UNIVERSITY OF MANCHESTER) 6 February 1985 see claims 1-3	1,10-12
A	US, A, 4486387 (AUGURT) 4 December 1984 see claims 1,3	1,10-12
A	GB, A, 1215891 (MAXWELL) 16 December 1970	
A	EP, A, 0069037 (CHARVIN) 5 January 1983	

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* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
2nd July 1987	-4 AUG 1987
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. VAN MOL

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 87/00125 (SA 16252)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/07/87

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
GB-A- 1458553	15/12/76	None		
GB-A- 2143322	06/02/85	EP-A-	0132107	23/01/85
US-A- 4486387	04/12/84	None		
GB-A- 1215891	16/12/70	None		
EP-A- 0069037	05/01/83	FR-A,B	2508317	31/12/82