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(54) ALLERGY TESTING DEVICE

ALLERGIETESTVORRICHTUNG

DISPOSITIF DE TEST D'ALLERGIES

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Description

[0001] This disclosure generally relates to reducing pain in a skin testing device system commonly used for applying test solution, such as liquid antigens, employed in skin testing for allergies, to patients' skin via skin test devices that have sharp pointed ends.

[0002] Skin testing to identify potential allergens that a patient may be allergic to is well known in many forms. The person conducting the skin testing may apply a relatively large number of test solutions to a patient's skin. To perform skin tests of this type, the person conducting the skin test typically places the skin test devices into a test solution such that a small amount of test solution adheres to the sharp pointed ends on the legs of the skin testing device via capillary attraction. The loaded skin test device is then pressed into a site on the patient's skin in a predetermined sequence. However, the sharp pointed ends of the skin test device may cause discomfort to some patients and much pain to other patients because the sharp pointed ends must penetrate the epidermis of the skin in order to get meaningful allergy test results. The discomfort and/or pain caused by the testing can be traumatic for the patient and disruptive to the nurse or doctor administering the testing.

[0003] US 2010/0022910 A1, US 2005/0137531 A1 and US 2007/0232956 A1 disclose devices for allergy skin testing.

[0004] The invention provides a skin test device as recited in claim 1. In an exemplary embodiment, an allergy testing system is disclosed. The allergy testing system comprises a skin test device and a plurality of wells, each having a reservoir for receiving test solutions such as potential allergens or controls. The skin test device can have an elongated grip portion for holding the device. A plurality of legs extends from the grip, and the plurality of legs is spaced and oriented to contact a corresponding well containing the test solution. Each of the plurality of legs has a test head, and each test head has a plurality of elongated spike members. The elongated spike members have sharp ends configured to receive the test solution or potential allergen from a well, for example via capillary attraction, and to puncture a patient's skin to deliver the test solution or allergen. In addition, each test head has at least one touch activator. The touch activator is longer than the plurality of elongated spike members, such that during an allergy test, the touch activator comes into contact with the skin prior to the elongated spike members, causing the touch activator to activate nerve tissue that blocks pain transmission resulting in a reduction of discomfort and/or pain during testing. Each well reservoir is sized and oriented to receive a separate test head of the allergy testing applicator.

[0005] It will be appreciated by those skilled in the art, given the benefit of the following description of certain exemplary embodiments disclosed herein, that at least some of these embodiments have improved or alternative configurations suitable to provide enhanced benefits. These and other aspects, features and advantages of this disclosure or of certain embodiments of the disclosure will be further understood by those skilled in the art from the following description of exemplary embodiments taken in conjunction with the following drawings.

[0006] To understand the present disclosure, it will now be described by way of example, with reference to the accompanying drawings in which:

FIG. 1 shows a perspective view of a skin testing device in accordance with an exemplary embodiment;

FIG. 2 shows a magnified perspective view of a test head in accordance with an exemplary embodiment.

FIG. 3 shows a bottom view of the exemplary embodiment shown in FIG. 2.

FIG. 4 shows a front view of the exemplary embodiment shown in FIG. 2, wherein the rear view is a mirror image of FIG. 4.

FIG. 5 shows a right side view of the exemplary embodiment shown in FIG. 2, wherein the left side view is a mirror image of FIG. 5.

[0007] While this disclosure is susceptible of embodiments in many different forms, there are shown in the drawings and will herein be described in detail exemplary embodiments with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiments illustrated.

[0008] The embodiments disclosed herein are adaptations of the neurological gate-control theory to help reduce the amount of pain felt by the patient during allergy skin testing. The neurological gate-control theory involves the activation of nerve cells that block pain transmission resulting in pain suppression. This theory of pain acknowledges that activation of nerves that do not transmit pain signals can restrict transmission signals from pain fibers and inhibit pain perception.

[0009] As shown in FIG. 1, an exemplary skin test device 10 is shown having a plurality of test legs 12, although a device with a single leg is also contemplated. The skin test device 10 has an elongated grip portion 18 for holding the device. The test legs 12 extend from the grip 18 and are spaced and oriented to come into contact with corresponding wells 16 containing test solutions or allergens prior to being placed into contact with the skin of a patient. The skin test device 10 can be provided with an extension 22, which can be formed in the shape of a "T" on the elongated grip 18 to ensure that the skin test device 10 is placed into the wells 16 in the proper orientation as is disclosed in U.S. Patent No. 5,792,071 to Hein.

[0010] Each elongated gripping portion 18 can be provided with one or more test heads 14, which are described in more detail below. Each of the test heads 14 are preferably shaped for being dipped into a series of

wells 16. When the test heads 14 are placed into the wells, the test solution in the corresponding well 16 adheres to the corresponding test head 14. The test heads 14, which can be approximately 0.15 in. in diameter, are configured to be placed into contact with a patient's skin to apply the test solution and to determine whether the patient reacts positively to a particular allergen - indicating that the patient is allergic to that allergen.

[0011] The series of wells 16 each have a reservoir for receiving test solutions such as potential allergens or control solutions. A different test solution, such as an allergen or a control solution is placed into each reservoir, e.g., by using a dropper or any other suitable method known in the art. Each reservoir is sized and oriented to receive a separate test head 14 of the skin test device 10. The test wells 16 can be provided with guide tabs 20 for preventing the reversing of the skin test device 10 position in the wells 16.

[0012] FIG. 2 shows a perspective view of an exemplary test head, which can be used in conjunction with the skin test device 10 shown in FIG. 1. The test head of FIGS. 2-5 can be located at each end of the test legs 12 as shown in FIG. 1. The test head is provided with a plurality of elongated spikes 202 each having a sharp pointed end 204. The elongated spikes 202 can have the shape of a pyramid, with a base formed in a square shape. It is noted, however, that other suitable shapes of the elongated spikes 202 are also contemplated.

[0013] The exemplary test head shown in FIGS. 2-5 also has a touch activator formed as touch post 206, which can be formed as a cylinder with a blunt convex top end 208. It is noted, however, that other suitable shapes of the touch post 206 are also contemplated. The blunt convex end 208 can be configured slightly longer than the elongated spikes 202 such that the convex end 208 of the touch post 206 makes contact with the patient's skin prior to the sharp pointed ends 204 of the elongated spikes 202.

[0014] As shown in FIG. 3, which is a bottom view of the exemplary test head, the test head can be provided with six elongated spikes 202; however, it is contemplated that different numbers of spikes can be used to accomplish acceptable allergy test results. For example, it is believed that the test head ideally may have between 3 and 6 spikes, but with smaller skin reactions with less than 6 spikes. The elongated spikes 202 can be arranged circumferentially around the touch post 206. However, other arrangements of the elongated spikes 202 and the touch post 206 are also contemplated. The arrangement shown in FIGS. 2-5 advantageously provides uniform loads of testing solutions on each test head during testing.

[0015] Again, the shapes and arrangements of the components described in the embodiments above are merely exemplary; other shapes and arrangements are also contemplated. In FIGS. 2-5, the touch activators are longer than the elongated spikes, such that the touch activators always come into contact with the patient's skin prior to the elongated spikes. This is necessary to provide adequate pain gate control or activation of nerve cells that block pain transmission, which results in pain suppression.

[0016] In the above embodiments, each of the elongated spikes can be manufactured at the same length and can all be the same length shorter than the touch activator(s). In addition, in the above embodiments, the touch activators can be manufactured at the same height so that the touch activators are the same length longer than the elongated spikes. However, arranging the elongated spikes at different lengths on the same or different test heads is also contemplated. Also length variances may occur due to manufacturing capabilities. However, it is noted that setting the touch activators at the same length as the elongated spikes will still produce satisfactory wheal sizes or allergy test results, but without the relief of pain to the patient.

[0017] Referring back to FIG. 1, in one exemplary process for using the system, the health care administrator of the test may place the test heads 14 into the series of wells 16. The guide 20 in conjunction with the extension 22 on the elongated grip 18 ensures that the allergy testing applicator 10 is placed into the wells 16 in the proper orientation reducing the possibility of testing errors. The test heads 14 are configured to receive test solutions, such as potential allergens or control solutions, from the series of wells 16. During use, the test heads 14 are pressed firmly into contact with the skin of the patient. The touch activators come into contact with the skin before the elongated spikes, such that the touch activators activate nerve tissue that blocks pain, resulting in a reduction of pain and/or discomfort during testing. During use, the elongated spikes of the test heads 14 puncture the skin and administer the allergens, but, the patient will feel less pain from the elongated spikes. The test administrator may subsequently interpret the results to determine whether the patient is allergic to a particular allergen.

[0018] In the exemplary embodiments, the touch activators activate nerve cells that inhibit pain, while sharp refined points apply the test solution. The refined points provide well-defined wheals with very little tissue trauma. This design provides high sensitivity, high specificity, and low variability in results with little pain felt by the patient.

[0019] It has been discovered that there is an ideal distance between the top of the touch activators and the ends of the elongated spikes for realizing pain suppression, while also gaining sufficient penetration of the pointed ends. Lengths of touch activators in the range of approximately 0.005 in. to 0.010 in. longer than the elongated spikes (when measured from the top of the touch activator to the tip or sharp point of the elongated spikes) provide acceptable results. As discussed below, providing touch activators that are 0.007 in. to 0.010 in. longer than the elongated spikes provided the best test results for the disclosed embodiments while suppressing meaningful pain felt by the subjects. As further discussed be-

low, a difference in length of 0.010 in. between the touch activators and elongated spikes provided the best observed results. However, it may be the case that different distances between the top of the touch activators and the ends of the elongated spikes are suitable in other arrangements and configurations of allergy skin testing devices. The test results are described below in more detail.

[0020] In the first test, the top of the touch activators were manufactured flush with the ends of the elongated spikes. No pain relief was observed, but the tests provided satisfactory wheal sizes from histamine at 1 mg/ml.

[0021] In the second test, the top of the touch activators were manufactured 0.003 in. longer than the ends of the elongated spikes. No pain relief was observed; however, the tests provided satisfactory wheal sizes from histamine.

[0022] In the third test, the top of the touch activators were manufactured 0.005 in. longer than the ends of the elongated spikes. Some reduction of pain was observed, and the tests provided satisfactory wheal sizes.

[0023] In the fourth test, the top of the touch activators were manufactured 0.007 in. longer than the ends of the elongated spikes. A meaningful reduction of pain was observed, and the tests provided satisfactory wheal sizes.

[0024] In the fifth test, the top of the touch activators were manufactured 0.010 in. longer than the ends of the elongated spikes. Virtually no pain was observed by the subjects, and the tests provided satisfactory wheal sizes that averaged 7 mm in diameter with very low variation in wheal sizes.

[0025] Incorporating the touch activators on the same test head as the elongated spikes provides many benefits. Previously, many allergists placed drops of extract on the skin and then pricked through the skin at the drops with a metal point; however, this practice is no longer widely used. Most doctors handling allergy diagnosis use self-loading devices that involve immersion of the points into testing solutions, allowing the points to load via capillary attraction. By incorporating the pain suppresser near the pain producer on the same test head, the skin testing devices can be immersed easily into the wells 16 shown in FIG 1. The dimensions of the exemplary skin testing devices disclosed herein can remain the same as those on other skin testing devices currently manufactured, such as those by the current assignee Lincoln Diagnostics, Inc. Consequently, the elongated spikes of the skin testing devices disclosed herein can be dipped into the currently existing wells.

[0026] Also by incorporating the touch activator and the elongated spikes on the same test head, it is simpler to inspect the devices for compliance with the critical length dimensions described above and to package them. In contrast, the use of pain suppressers separated from each test head would make inspection more complex and require larger and more complex unit containers.

[0027] Devices that employ the pain suppressers separated from the test head are difficult and impractical to use with existing wells containing test solutions. In these devices, it would also be difficult to accomplish reliable self-loading of allergen extracts via capillary attraction. Additionally, less plastic is used when the touch activator and the elongated spikes are incorporated onto the same test head.

[0028] Also, for the skin testing devices disclosed herein, the amount of test solution is less in volume than that for the previous skin testing devices because of the arrangement of the elongated spikes and the touch activators. The end result is more test sites from a 5 ml vial of test solutions, such as allergens, allergenic extracts, and controls.

[0029] Given the benefit of the above disclosure and description of exemplary embodiments, it will be apparent to those skilled in the art that numerous alternative and different embodiments are possible in keeping with the scope of the invention as defined by the claims. The appended claims are intended to cover all such modifications and alternative embodiments. It should be understood that the use of a singular indefinite or definite article (e.g., "a," "an," "the," etc.) in this disclosure and in the following claims follows the traditional approach in patents of meaning "at least one" unless in a particular instance it is clear from context that the term is intended in that particular instance to mean specifically one and only one. Likewise, the term "comprising" is open ended, not excluding additional items, features, components, etc.

Claims

1. A skin test device for allergy testing comprising:

a grip portion (18) for holding the skin test device;

at least one leg (12) extending from the grip portion, the leg being oriented to interact with a well (16) containing a test solution;

wherein the leg has a test head (14), the test head being configured to be dipped into the well, the test head having a plurality of elongated spikes (202;302;402;502) each having a sharp end (204;304;404) configured to receive the test solution from the well and to be removed from the well, and to puncture skin for delivering the test solution,

the test head having at least one touch activator (208;308;408;508) wherein the touch activator is longer than the elongated spikes and does not move relative to the elongated spikes, such that during use, the touch activator comes into contact with the skin prior to the elongated spikes, causing the touch activator to activate nerve tissue that suppresses pain, resulting in a reduction of pain during testing;

the skin test device **characterized in that** the elon-

gated spikes surround the touch activator.

2. The skin test device of claim 1, wherein the touch activator on the test head (14) has a convex end portion (208).

3. The skin test device of claim 1, wherein the touch activator on the test head (14) is a cylindrical shaped post (206).

4. The skin test device of claim 1, wherein the elongated spikes (202;302;402;502) is pyramid shaped, and wherein the base of the elongated spikes is square shaped.

5. The skin test device of any preceding claim, wherein each touch activator (208;308;408;508) is in the range of 0.005 in. (0.1 mm) to 0.010 in. (0.3 mm) longer than the longest of the elongated spikes (202;302;402;502).

6. An allergy testing system comprising:

a skin test device as claimed in any preceding claim and comprising a plurality of said legs (12) and said test heads (14); and
a plurality of wells (16) each well having a reservoir for receiving test solutions and wherein each reservoir is sized and oriented to receive a separate test head of the skin test device.

Patentansprüche

1. Hauttestvorrichtung für einen Allergietest, umfassend:

einen Griffabschnitt (18) zum Halten der Hauttestvorrichtung;
zumindest ein Bein (12), das sich von dem Griffabschnitt erstreckt, wobei das Bein ausgerichtet ist, um mit einer Vertiefung (16), die eine Testlösung enthält, zu interagieren;
wobei das Bein einen Testkopf (14) aufweist, wobei der Testkopf dazu konfiguriert ist, um in die Vertiefung eingetaucht zu werden, wobei der Testkopf eine Vielzahl von länglichen Stiften (202; 302; 402; 502) aufweist, die jeweils ein spitzes Ende (204; 304; 404) aufweisen, das konfiguriert ist, um die Testlösung aus der Vertiefung zu empfangen und aus der Vertiefung entfernt zu werden und Haut zu durchstechen, um die Testlösung abzugeben,
wobei der Testkopf zumindest einen Berührungsaktivator (208; 308; 408; 508) aufweist, wobei der Berührungsaktivator länger als die länglichen Stifte ist und sich nicht relativ zu den länglichen Stiften bewegt, so dass der Berührungsaktivator während einer Verwendung vor den länglichen Stiften mit der Haut in Kontakt kommt, was bewirkt, dass der Berührungsaktivator Nervengewebe aktiviert, das Schmerz unterdrückt, was zu einer Schmerzreduzierung während dem Test führt;
wobei die Hauttestvorrichtung **dadurch gekennzeichnet ist, dass** die länglichen Stifte den Berührungsaktivator umgeben.

2. Hauttestvorrichtung nach Anspruch 1, wobei der Berührungsaktivator an dem Testkopf (14) einen konvexen Endabschnitt (208) aufweist.

3. Hauttestvorrichtung nach Anspruch 1, wobei der Berührungsaktivator an dem Testkopf (14) ein zylindrisch geformter Pfosten (206) ist.

4. Hauttestvorrichtung nach Anspruch 1, wobei die länglichen Stifte (202; 302; 402; 502) pyramidenförmig sind und wobei die Basis der länglichen Stifte viereckförmig ist.

5. Hauttestvorrichtung nach einem vorstehenden Anspruch, wobei jeder Berührungsaktivator (208; 308; 408; 508) in dem Bereich von 0,005 Zoll (0,1 mm) bis 0,010 Zoll (0,3 mm) länger als die längste von den länglichen Stiften (202; 302; 402; 502) ist.

6. Allergietestsystem, umfassend:

eine Hauttestvorrichtung nach einem vorstehenden Anspruch und umfassend eine Vielzahl der Beine (12) und der Testköpfe (14); und
eine Vielzahl von Vertiefungen (16), wobei jede Vertiefung einen Behälter zum Empfangen von Testlösungen aufweist und wobei jeder Behälter bemessen und ausgerichtet ist, um einen separaten Testkopf der Hauttestvorrichtung zu empfangen.

Revendications

1. Dispositif destiné à un test cutané pour une épreuve allergique, comprenant :

une portion de préhension (18) pour tenir le dispositif destiné à un test cutané ;
au moins une branche (12) s'étendant à partir de la portion de préhension, la branche étant orientée pour entrer en interaction avec un puits (16) contenant une solution test ;
dans lequel la branche possède une tête de test (14), la tête de test étant configurée pour être plongée dans le puits, la tête de test possédant plusieurs pointes allongées (202 ; 302 ; 402 ; 502) possédant chacune une extrémité pointue

(204 ; 304 ; 404) configurées pour recevoir la solution test à partir du puits et pour être retirées du puits, et pour perforer la peau pour la distribution de la solution test ;
la tête de test possédant au moins un activateur tactile (208 ; 308 ; 408 ; 508), l'activateur tactile étant plus long que les pointes allongées et étant immobile par rapport aux pointes allongées de manière telle que lors de l'utilisation l'activateur tactile entre en contact avec la peau avant les pointes allongées en faisant en sorte que l'activateur tactile active le tissu nerveux qui supprime la douleur, donnant lieu à une réduction de la douleur au cours de l'épreuve ;
le dispositif destiné à un test cutané étant **caractérisé en ce que** les pointes allongées entourent l'activateur tactile.

2. Dispositif destiné à un test cutané selon la revendication 1, dans lequel l'activateur tactile sur la tête de test (14) possède une portion terminale convexe (208).

3. Dispositif destiné à un test cutané selon la revendication 1, dans lequel l'activateur tactile sur la tête de test (14) est une tige (206) de configuration cylindrique.

4. Dispositif destiné à un test cutané selon la revendication 1, dans lequel les pointes allongées (202 ; 302 ; 402 ; 502) sont de configuration pyramidale et dans lequel la base des pointes allongées est de configuration carrée.

5. Dispositif destiné à un test cutané selon l'une quelconque des revendications précédentes, dans lequel chaque activateur tactile (208 ; 308 ; 408 ; 508) est plus long dans la plage de 0,005 pouce (0,1 mm) à 0,010 pouce (0,3 mm) que la plus longue des pointes allongées (202 ; 302 ; 402 ; 502).

6. Système pour une épreuve allergique comprenant :

un dispositif destiné à un test cutané tel que revendiqué dans l'une quelconque des revendications précédentes et comprenant un certain nombre desdites branches (12) et desdites têtes de test (14) ; et
un certain nombre de puits (16), chaque puits possédant un réservoir pour la réception de solutions test et dans lequel chaque réservoir est dimensionné et orienté pour recevoir une tête de test séparée du dispositif destiné à un test cutané.

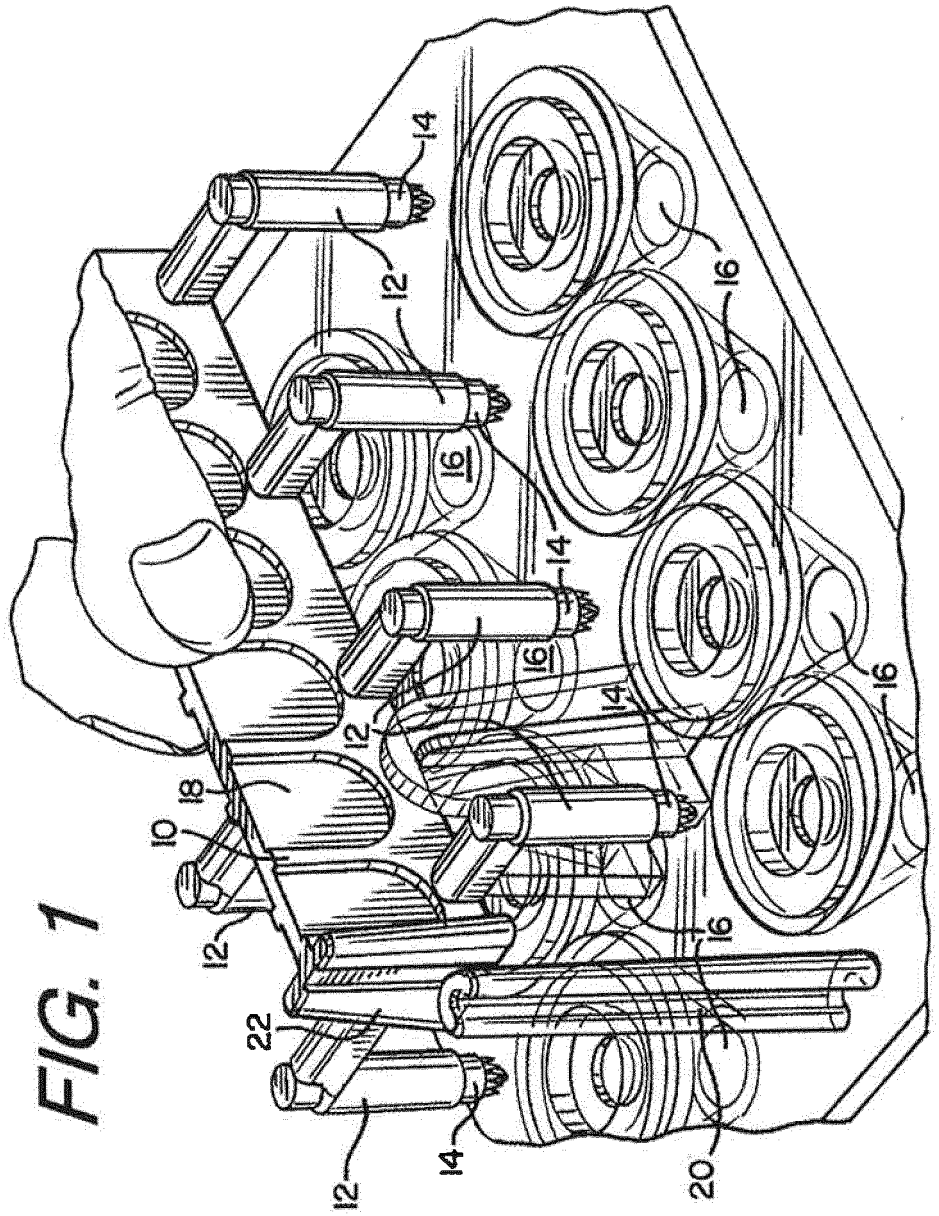


FIG. 1

FIG. 2

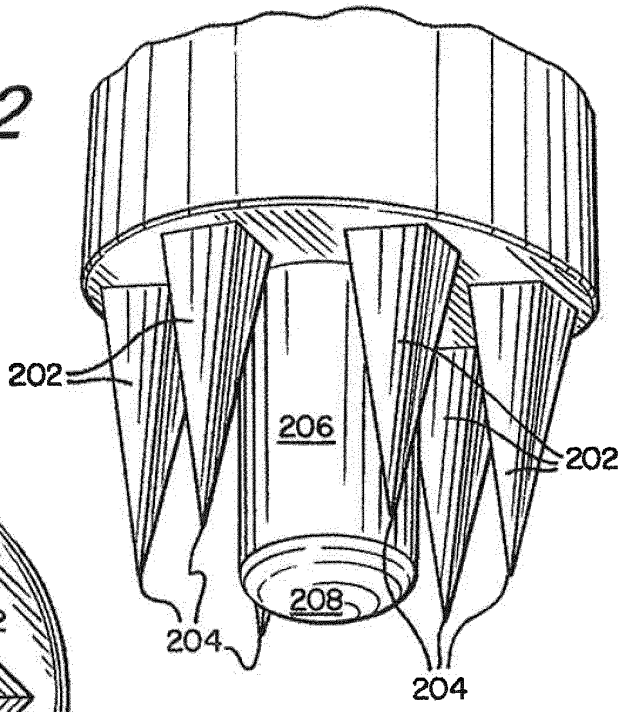


FIG. 3

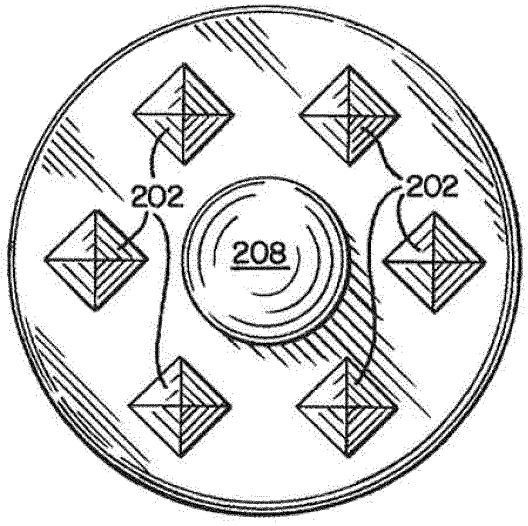
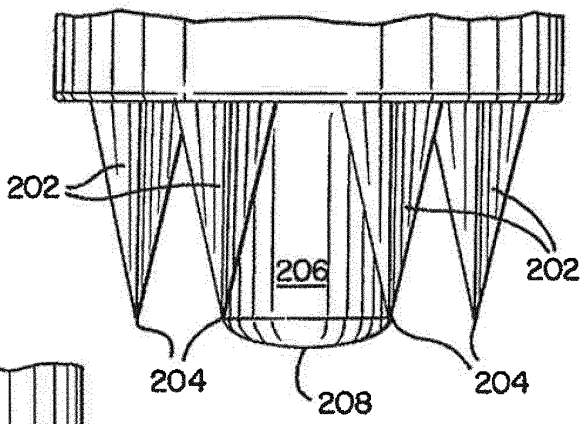


FIG. 4



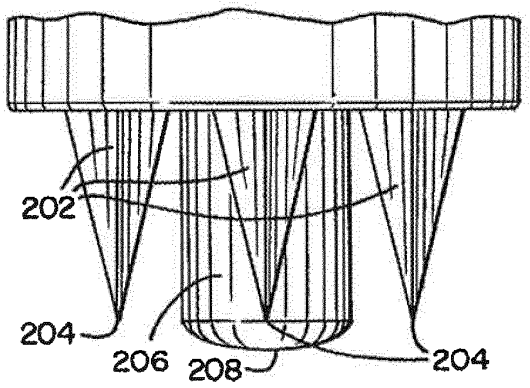


FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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摘要(译)

过敏测试系统包括皮肤测试装置，该皮肤测试装置具有用于保持该装置的抓握部分。一个或多个腿从手柄延伸，并且每个腿定向成与包含潜在过敏原的孔相互作用。每个腿具有测试头，并且每个测试头具有多个细长的钉状构件。细长的尖钉构件具有尖端，该尖端构造成从井接收潜在的过敏原并刺穿患者的皮肤。此外，每个测试头具有至少一个触摸激活器。触摸激活器比多个细长尖钉构件长，使得在过敏测试期间，触摸激活器在细长尖钉构件之前与皮肤接触，使触摸激活器激活阻止疼痛传递的神经组织，在测试过程中减少疼痛和/或不适。