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(54) Titre : PROCEDE ET APPAREIL D'ANALYSE NON INVASIVE DE LA SALIVE
(54) Title: METHOD AND APPARATUS FOR NON-INVASIVE ANALYSIS OF SALIVA

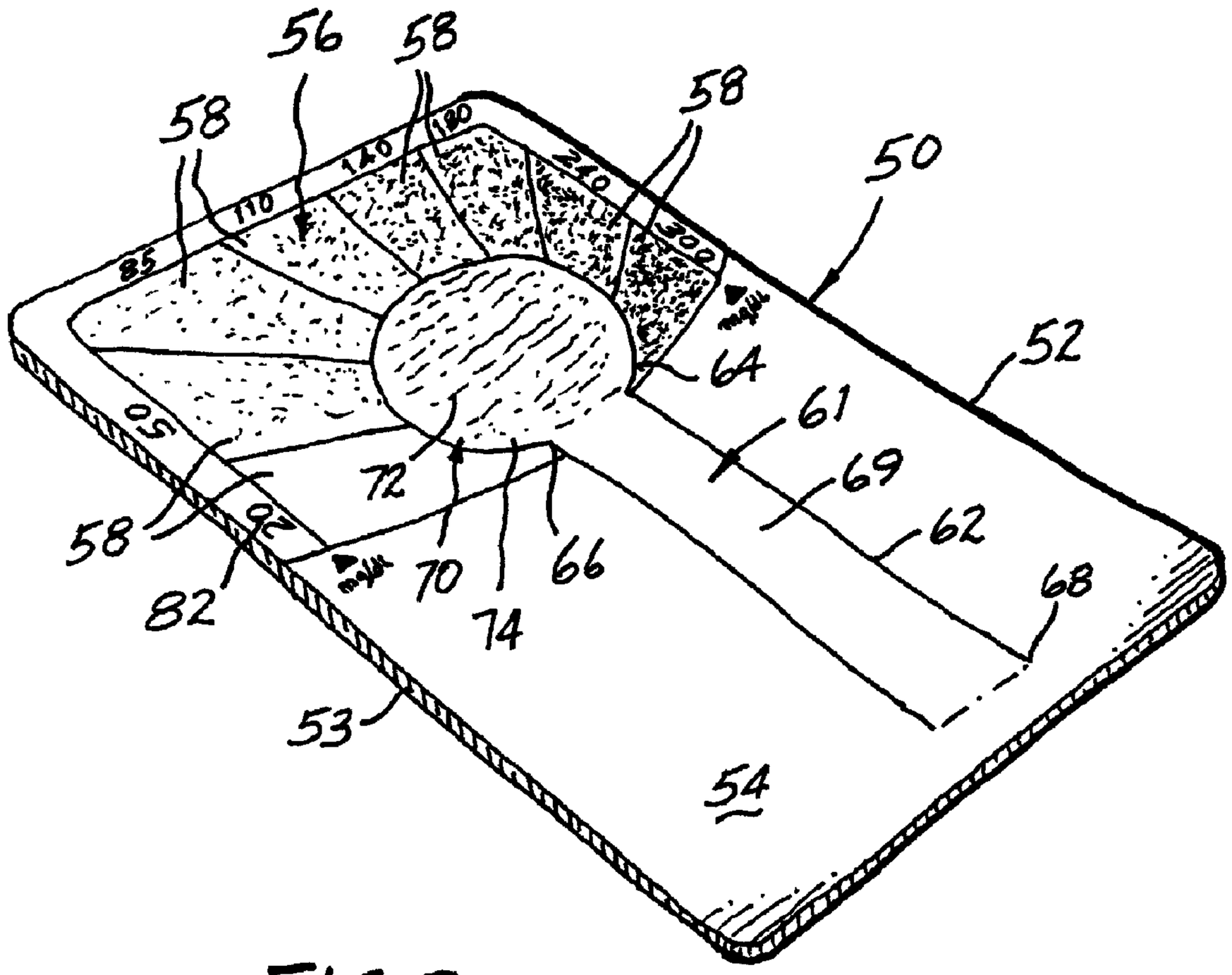


FIG. 3

(57) Abrégé/Abstract:
A method and apparatus for non-invasive analysis of an oral fluid, such as saliva, to determine the presence and the level of a certain constituent in the saliva The apparatus includes a user-friendly, lolli-pop like construction that is self-contained and provides

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(57) Abrégé(suite)/Abstract(continued):
a user with a method to obtain a saliva sample by sucking or licking a pop-like head of the apparatus. A reagent on the apparatus is exposed to the saliva sample and interacts with the certain constituent to produce a color change made visible on the apparatus. The resulting visible color change is then matched visually with a corresponding color on a color-coded alphanumeric gauge for determining the presence and the level of the certain constituent in the saliva sample, thereby providing quick and simple monitoring of health conditions and concerns.

# METHOD AND APPARATUS FOR NON-INVASIVE ANALYSIS OF SALIVA

## Abstract of the Disclosure

A method and apparatus for non-invasive analysis of an oral fluid, such as saliva, to determine the presence and the level of a certain constituent in the saliva. The apparatus includes a user-friendly, lolli-pop like construction that is self-contained and provides a user with a method to obtain a saliva sample by sucking or licking a pop-like head of the apparatus. A reagent on the apparatus is exposed to the saliva sample and interacts with the certain constituent to produce a color change made visible on the apparatus. The resulting visible color change is then matched visually with a corresponding color on a color-coded alphanumeric gauge for determining the presence and the level of the certain constituent in the saliva sample, thereby providing quick and simple monitoring of health conditions and concerns.

# METHOD AND APPARATUS FOR NON-INVASIVE ANALYSIS OF SALIVA

The present invention relates generally to the analysis of an oral fluid, such as saliva, utilizing a user-friendly lolli-pop-like apparatus and pertains, more specifically, to a non-invasive apparatus and method which can expose a sample of an oral fluid, such as saliva, to a reagent that will undergo a color change in response to such exposure and thereby provide a visible color change which can be viewed and compared to a visible gauge to determine the presence and level of a particular constituent in the saliva sample.

The need for self-monitoring in connection with a variety of ailments and conditions has grown exponentially over the years. Testing needs range from diabetes glucose levels, to alcohol levels to pregnancy, and more. For example, the near epidemic rise in diabetes throughout the world has resulted in a need for a less invasive apparatus and method for testing glucose levels. Current methods for testing and monitoring most often result in a user having to provide blood samples to monitor a condition. The rise in alcoholism and binge drinking has resulted in a need for self-monitoring to prevent ambulatory or law enforcement intervention. The increase in illicit drug use, both by the casual user and by an addict, has resulted in the need for individuals, for workers at a workplace, as well as for entire families, to have a low cost means to monitor drug use. These are but a few of the applications in which it would be advantageous to have available a low cost, disposable, user-friendly device for use in a simple procedure.

The present invention provides such an apparatus and method and, as such attains several objects and advantages, some of which are summarized as follows: Provides a user-friendly, non-invasive mode for testing which allows the use of a less expensive apparatus suitable for more

widespread use and acceptance; enables greater convenience in carrying about and using a simple apparatus for reliable testing; allows greater convenience in purchasing and maintaining a supply of testing apparatus; provides a simplified and reliable visual mode for monitoring test results; reduces potential hazards of incorrect evaluation of results; enables the economical manufacture and distribution of relatively low-cost, reliable diagnostic test apparatus, thereby opening new and larger markets for testing apparatus.

The above objects and advantages, as well as further objects and advantages, are attained by the present invention which may be described briefly as apparatus for conducting a non-invasive analysis of saliva to determine the presence and the level of a certain constituent carried by the saliva, the apparatus comprising: a base a visible gauge on the base, the visible gauge including an interpretation site and visible regions of different colors displayed upon the base adjacent the interpretation site; a lolli-pop-like structure including a stem and a head integrated with the stem, the stem including a finger-grip, and the head including a receptor for the reception of a saliva sample; the stem being selectively movable by a user between a first position, wherein the head is spaced from the base and the stem extends away from the base to expose the finger-grip for gripping by the user, and a second position wherein the stem is retracted toward the base to place the receptor of the head at the interpretation site, in juxtaposition with the visible gauge; and a reagent carried by one of the head at the receptor and the base at the interpretation site, the reagent being capable of changing color in response to exposure to the certain constituent, such that upon placement of the stem in the first position, the finger-grip is available for engagement by the user with the receptor exposed for receiving the saliva sample, and upon subsequent placement of the stem in the second position, the receptor is juxtaposed with the interpretation site so that any change

in color of the reagent in response to exposure of the reagent to the saliva sample will be visibly registered with the regions of different colors of the visible gauge for enabling a direct visual matching of the change in color of the reagent with a corresponding color of a visible region of the visible gauge, thereby providing a directly readable indication of the presence and the level of the certain constituent in the saliva sample.

In addition, the present invention provides a method for conducting a non-invasive analysis of saliva to determine the presence and the level of a certain constituent carried by the saliva, the method comprising: providing a base having a visible gauge on a surface of the base, the visible gauge including an interpretation site and visible regions of different colors displayed upon the base adjacent the interpretation site; providing a lolli-pop-like structure including a stem and a head integrated with the stem, the stem including a finger-grip, and the head including a receptor for the reception of a saliva sample; providing a reagent carried by one of the head at the receptor and the base at the interpretation site, the reagent being capable of changing color in response to exposure to the certain constituent; placing a saliva sample on the receptor when the stem is in a first position wherein the head and the stem are away from the base; and moving the stem to a second position wherein the receptor of the head is placed at the interpretation site, in juxtaposition with the visible gauge, such that upon placement of the stem in the second position, the receptor is juxtaposed with the interpretation site so that any change in color of the reagent in response to exposure of the reagent to the saliva sample is visibly registered with the regions of different colors of the visible gauge for enabling a direct visual matching of the change in color of the reagent with a corresponding color of a visible region of the visible gauge, thereby establishing a directly readable indication of the presence and the level of the certain constituent in the saliva sample.

The invention will be understood more fully, while still further objects and advantages will become apparent, in the following detailed description of preferred embodiments of the invention illustrated in the accompanying drawings, in which:

FIG. 1 is a pictorial view of an apparatus constructed for use in accordance with the present invention;

FIG. 2 is a pictorial view showing another apparatus constructed for use in accordance with the present invention;

FIG. 3 is a pictorial view of a compact, non-invasive apparatus constructed in accordance with the present invention;

FIG. 4 is a pictorial view similar to FIG. 3 and showing the apparatus in another stage of use in accordance with the present invention;

FIG. 5 is a pictorial view showing a step in the method of use of the apparatus in accordance with the present invention;

FIG. 6 is a pictorial view showing another step in the method;

FIG. 7 is a pictorial view showing an alternate embodiment of the invention, with FIGS. 7A through 7D demonstrating steps of an alternate method of the present invention; and

FIG. 8 is a pictorial view showing another alternate embodiment of the present invention.

Referring now to the drawing, and especially to FIG. 1 thereof, an apparatus for non-invasive analysis of an oral fluid in the form of saliva, for the presence and the level of a certain specific constituent in the saliva, is constructed for use in accordance with the present invention and is shown at 10. Apparatus 10 is constructed in the form of a lolli-pop-like structure 12 having a pop-like head 14 which includes a reagent 15 carried on a reagent surface 16 of the

head 14, a stem 18, a porous filter 20, preferably constructed of paper or a synthetic polymeric material, and a saliva-holding chamber 22. Reagent 15 is capable of changing color in response to exposure to the specific constituent which is the subject of the analysis to provide an indication of the presence and the level of that certain constituent in the saliva sample, as will be described in greater detail below. Apparatus 10 is activated by squeezing a suction ball 24, located at the bottom 26 of stem 18.

A user (not shown) will hold the apparatus 10 at the stem 18, will either lick or suck on the pop-like head 14, thereby generating a saliva sample at the surface 16 of the head 14, and exposing the reagent 15 to the saliva sample. The user then will squeeze the suction ball 24, and the saliva sample gathered on the surface 16 of head 14, now mixed with reagent 15, will enter a top opening 28 will flow through the filter 20 and will be retained at the holding chamber 22 of the stem 18 awaiting the observation of any color change as the saliva interacts with the reagent 15 carried in the saliva sample. Once any color change is complete, the resulting color is compared to a color-coded alphanumeric gauge to determine the presence and the level of the certain constituent.

Turning now to FIG. 2, another apparatus constructed for non-invasive analysis of saliva in accordance with the present invention is shown at 30. Apparatus 30 includes a lolli-pop-like structure 32 in which a pop-like head 34 carries a reagent 35 on a reagent surface 36. A stem 38 provides a finger-grip 40 which enables a user (not shown) to hold the apparatus 30 while the user sucks on or licks the pop-like head 34. As before, reagent 35 is exposed to a saliva sample thus placed on the head 34, and the head 34 will display a change in color as a result of the interaction between the saliva and the reagent 35. The resulting color then is compared to a color-coded alphanumeric gauge to match colors and determine the presence and the level of the specific certain

constituent to which the reagent 35 is related.

Referring now to FIGS. 3 through 6, an apparatus constructed in accordance with the present invention for use in conducting a non-invasive analysis of an oral fluid, such as saliva, in accordance with the present invention, is shown at 50. Apparatus 50 is in the form of a thin, card-like structure having a substantially flat, card-like body 52 constructed of a selectively bendable material such as, for example, card stock or a synthetic polymeric material. Body 52 provides a base 53 and has an essentially flat upper surface 54, and a visible gauge 56 is displayed on the upper surface 54, as by printing various elements of the gauge 56 upon the surface 54. The various elements of the visible gauge 56 include visible regions 58 juxtaposed with an interpretation site 60, the regions 58 being arrayed about the interpretation site 60. Each region 58 is of a different color, for purposes to be set forth below.

A lolli-pop-like structure 61 includes a stem 62 and a pop-like head 64 integral with the stem 62 at a distal end 66 of the stem 62. The stem 62 is coupled with the body 52 at a proximal end 68 of the stem 62 and includes a finger-grip 69 intermediate the ends 66 and 68. In the preferred construction, the stem 62 and the head 64 are die-cut from the remainder of the body 52 to sever the head 64 from the base 53 and the stem 62 from the base 53, between the ends 66 and 68 of the stem 62, with the stem 62 and the head 64 being unitary, and the stem 62 being unitary with the body 52 at the proximal end 68. The head 64 includes a receptor 70 and a reagent 72 is carried by the head 64, at the receptor 70, the reagent 72 being placed upon a reagent surface 74 at the receptor 70. Apparatus 50 is provided for conducting a non-invasive analysis of saliva to determine the presence and the level of a certain constituent carried by the saliva. Reagent 72 is selected for the capability of changing color in response to exposure to the certain constituent, to

indicate the presence and the level of the certain constituent, as will be set forth in greater detail below.

Apparatus 50 is furnished in the flat, card-like configuration illustrated in FIG. 3, with the lolli-pop-like structure 61 embedded within body 52, substantially flush with the upper surface 64. In that configuration, apparatus 50 is conveniently stored and easily carried about. When apparatus 50 is to be put into use, the lolli-pop-like structure 61 is raised from the remainder of body 52 by moving the stem 62 to a position wherein the head 64 is raised from the base 53 and the stem 62 extends from the base 53 to the head 64, as illustrated in FIG. 4. To that end, the material of the body 52 is bent adjacent the proximal end 68 of the stem 62 to move the stem 62 and the head 64 to the position shown in FIG. 4. With the apparatus 50 configured as shown in FIG. 4, the head 64 is available for placement by a user 80 in position for either being sucked or licked, as illustrated in FIG. 5, such that a sample of saliva is received by the receptor 70 and the reagent 72 is exposed to the saliva sample. Manipulation of the stem 62, as well as the apparatus 50 itself, is facilitated by the finger-grip 69 which is made available for gripping when the stem 62 is raised from the base 53. A saliva stimulant may be included on head 64 to stimulate the generation of a saliva sample.

Once a saliva sample is placed on the receptor 70, the stem 64 is moved to a position wherein the stem 64 is retracted toward the base 53 and the receptor 70 is placed at the interpretation site 60, in juxtaposition with the visible gauge 56, as seen in FIG. 6. The color change effected by exposure of the reagent 72 to the saliva sample on the receptor 70 then is visibly registered with the regions 58 of different colors provided by gauge 56, enabling the user 80 to visually match the change in color of the reagent 72 with a corresponding color of a particular region 58, thereby obtaining a directly readable indication of the presence and the level of the

certain constituent in the saliva sample. Alpha-numeric characters 82 are displayed on the visible gauge 56 and are associated with each region 58 for further identifying the level of the certain constituent indicated by the visual matching of the color of the reagent 72 with a particular region 58. Once the analysis is complete, the apparatus 50 merely is discarded.

An alternate apparatus constructed in accordance with the present invention is illustrated in FIG. 7 at 100, and is seen to comprise a construction similar to that of apparatus 50. Accordingly, similar reference characters are employed to identify similar component parts. Thus, as seen in FIG. 7A, apparatus 100 includes a body 52 having a card-like construction, as before, and stem 62 carries head 64 for selective movement between the positions illustrated in FIGS. 7A and 7B. However, in apparatus 100, body 52 includes a basal layer 110, and a reagent surface 112 is provided at the interpretation site 60 by the basal layer 110. A reagent 120 is placed upon the reagent surface 112 of the basal layer 110, rather than on the head 64, as in the embodiment of FIGS. 3 through 6. A receptor 130 on the head 64 is provided with a saliva-receptive material, preferably in the form of a sponge-like member 132. Upon placement of the head 64 in position to be sucked or licked by the user 80, as shown in FIG. 7C, a saliva sample is provided to the receptor 130 while avoiding direct contact between the user 80 and the reagent 120.

Once a saliva sample is supplied to the receptor 130, the stem 62 is moved back to the position shown in FIG. 7A to expose the reagent 120 at the reagent surface 112 to the saliva sample carried by the receptor 130 and to allow the saliva sample to interact with the reagent 120 for effecting a color change. The stem 62 then is moved to the position shown in FIG. 7D, thereby raising the head 64 away from the interpretation site 60 and revealing the changed color of the reagent 120, which changed color is registered with the regions 58 of the visible gauge 56, enabling

the user 80 to visually match the change in color of the reagent 120 with a corresponding color of a particular region 58, thereby obtaining a directly readable indication of the presence and the level of the certain constituent in the saliva sample, all without the need for any direct contact of the user 80 with the chemistry of reagent 120.

Referring now to FIG. 8, another alternate apparatus constructed in accordance with the present invention is illustrated at 200, and is seen to comprise a construction similar to that of apparatus 50. Accordingly, similar reference characters are employed to identify similar component parts. Thus, apparatus 200 includes a body 52 having a card-like construction, as before; however, a plurality of stems 62 carry a corresponding plurality of heads 64 for selective movement between the positions described above in connection with apparatus 50. The multiple stems 62 each are attached to the body 52 at a corresponding proximal end 68, and are available for conducting separate tests, one at a time, with each lolli-pop-like structure 51 able to be torn torn from the body 52 for disposal after the completion of a corresponding analysis. In this manner, a single apparatus 200 is available for convenient use in conducting serial multiple analyses.

The selection of a reagent 70 or 120 is based upon the identity of the certain constituent sought in the analysis to be performed. The following are examples of reagents which can be used for determining the presence and the level of some of these certain constituents:

For glucose testing, the reagent chemistry can comprise: The enzymes glucose oxidase and peroxidase, a chromogen that produces a dye when reacted with hydrogen peroxide, a buffer to provide an appropriate pH for both enzymes, one or more surfactants that enhance color development and absorption of the fluid being tested, and other inert ingredients for enzyme stabilization or elimination of interfering substances.

For testing for alcohol levels, the test reagent chemistry can comprise: The enzymes alcohol oxidase and peroxidase, a chromogen that produces a dye when reacted with hydrogen peroxide, a buffer to provide an appropriate pH for both enzymes, one or more surfactants that enhance color development and absorption of the fluid being tested and other inert ingredients for enzyme stabilization or elimination of interfering substances.

For ketone level testing, the reagent chemistry can comprise: Nitroprusside, diazonium salt, and a buffer.

For cholesterol level testing, the reagent chemistry can comprise: The enzymes cholesterol oxidase, cholesterol esterase and peroxidase, a chromogen that produces a dye when reacted with hydrogen peroxide, a buffer to provide an appropriate pH for both enzymes, one or more surfactants that enhance color development and absorption of the fluid being tested and other inert ingredients for enzyme stabilization or elimination of interfering substances.

For cortisol level testing, the reagent chemistry can comprise: 11β-hydroxysteroid dehydrogenase [11β-HSD; EC:1.1.1.146(Acinetobacter sp. ADP1)], potassium ferricyanide (oxidizing agent), phosphate buffer (to maintain pH) and non-reactive ingredients such as a polyacrylamide. The 11β-HSD is modified to ferrocene-11β-HSD through a series of steps using sodium periodate and ferrocenecarboxylic acid to achieve maximum adsorption and conductivity. The ferrocene amendment occurs at the sugar groups of the enzymes. The modified 11β-HSD is also immobilized in a thin-layer cross-linked polyacrylanmide microgel using the concentrated emulsion polymerization method. The degree of cross linking determines water uptake, pore size and the molecular exclusion limit. In the mechanism of action, the 11β-hydroxysteroid dehydrogenase [11β-HSD; EC:1.1.1.146(Acinetobacter sp. ADP1)] catalysis the interconversion of

the 11β-hydroxy group of cortisol into its oxidized keto form. This reaction requires NADP as cofactor as cortisol is oxidized to cortisone and loses a proton, which then reduces NADP to NADPH+.

For illicit drug level testing, the reagent chemistry can comprise: Ion exchange resin, dinitrophenyl, an aryl hydrazine, and a stain such as Dragendorff test for alcoloids, nicotine, morphine, heroin naturally occurring compounds, sodium sulfate, or ninhydrin test for amino acide (proteins).

For pregnancy testing, the reagent chemistry can comprise: A phenolic derivative of N-acetyl-B-d-glucosamine for reaction to the presence of glucosaminidase at acid pH to allow it to form phenol with a specific color alkaline pH, along with a buffer.

For salicylate level testing, the reagent chemistry can comprise: Denatured alcohol with distilled water, ferric ammonium sulfate, magnesium sulfate heptahydrate, and cyclohexylsulfamic acid.

with a specific color alkaline pH, along with a buffer.

The above reagent compositions are given by way of example only. Other reagents are available and are know in the prior art.

The present invention provides a very compact and practical arrangement for analysis of saliva for health conditions. It will be seen that the present invention attains all of the objects and advantages summarized above, namely: Provides a user-friendly, non-invasive mode for testing which allows the use of a less expensive apparatus suitable for more widespread use and acceptance; enables greater convenience in carrying about and using a simple apparatus for reliable testing; allows greater convenience in purchasing and maintaining a supply of testing

apparatus; provides a simplified and reliable visual mode for monitoring test results; reduces potential hazards of incorrect evaluation of results; enables the economical manufacture and distribution of relatively low-cost, reliable diagnostic test apparatus, thereby opening new and larger markets for testing apparatus.

It is understood that the above detailed description of preferred embodiments of the invention is provided by way of example only. Various details of design, construction, procedure and chemistry may be modified without departing from the true spirit and scope of the invention, as set forth in the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. Apparatus for conducting a non-invasive analysis of saliva to determine the presence and the level of a certain constituent carried by the saliva, the apparatus comprising:

a base;

a visible gauge on the base, the visible gauge including an interpretation site and visible regions of different colors displayed upon the base adjacent the interpretation site;

a lolli-pop-like structure including a stem and a head integrated with the stem, the stem including a finger-grip, and the head including a receptor for the reception of a saliva sample;

the stem being selectively movable by a user between a first position, wherein the head is spaced from the base and the stem extends away from the base to expose the finger-grip for gripping by the user, and a second position wherein the stem is retracted toward the base to place the receptor of the head at the interpretation site, in juxtaposition with the visible gauge; and

a reagent carried by one of the head at the receptor and the base at the interpretation site, the reagent being capable of changing color in response to exposure to the certain constituent, such that upon placement of the stem in the first position, the finger-grip is available for engagement by the user with the receptor exposed for receiving the saliva sample, and upon subsequent placement of the stem in the second position, the receptor is juxtaposed with the interpretation site so that any change in color of the reagent in response to exposure of the reagent to the saliva sample will be visibly registered with the regions of different colors of the visible gauge for enabling a direct visual matching of the change in color

of the reagent with a corresponding color of a visible region of the visible gauge, thereby providing a directly readable indication of the presence and the level of the certain constituent in the saliva sample.

2. The apparatus of claim 1 wherein the base includes a card-like body having a substantially flat upper surface, the stem includes a first end and an opposite second end, the head is integral with the first end of the stem, and the second end of the stem is coupled with the body of the base for enabling selective movement of the stem between the first position, wherein the head is raised out of and above the upper surface of the body, and the second position, wherein the stem and the head are placed at the substantially flat upper surface of the body, and the visible gauge extends along the upper surface, in position to be juxtaposed with the head upon placement of the stem in the second position.

3. The apparatus of claim 2 wherein the card-like body is constructed of a selectively bendable material, and the lolli-pop-like structure is unitary with the body and severed along the stem between the first and second ends and along the head for selective bending of the material at the second end of the stem to move the stem between the first and second positions.

4. The apparatus of claim 2 wherein the card-like body includes a plurality of lolli-pop-like structures, each lolli-pop-like structure having a corresponding stem and a corresponding head, each corresponding stem being coupled with the body for selective movement between a corresponding first position and a corresponding second position, and each corresponding head being placed in juxtaposition with the visible gauge upon placement of the corresponding stem in the second position.

5. The apparatus of claim 1 wherein the reagent is carried by the head for exposure to the saliva sample at the receptor and subsequent juxtaposition with the visible gauge upon placement of the head in the second position.

6. The apparatus of claim 1 wherein the reagent is placed on the base, juxtaposed with the visible gauge and located for exposure to the saliva sample by engagement with the receptor upon placement of the head in the second position.

7. The apparatus of claim 1 including alpha-numeric characters displayed on the visible gauge, with each character being associated with a corresponding visible region for further identifying the level of the certain constituent indicated by the visual matching of the color of the reagent with a particular region of color.

8. The apparatus of claim 1 wherein the certain constituent is a glucose and the reagent is comprised of a chemical composition for changing color in response to a level of the glucose in the saliva sample.

9. The apparatus of claim 1 wherein the certain constituent is an alcohol and the reagent is comprised of a chemical composition for changing color in response to a level of the alcohol in the saliva sample.

10. The apparatus of claim 1 wherein the certain constituent is a ketone and the reagent is comprised of a chemical composition for changing color in response to a level of the ketone in the saliva sample.

11. The apparatus of claim 1 wherein the certain constituent is a predetermined drug and the reagent is comprised of a chemical composition for changing color in response to a level of the predetermined drug in the saliva sample.

12. The apparatus of claim 1 wherein the certain constituent is a pregnancy indicator and the reagent is comprised of a chemical composition for changing color in response to the pregnancy indicator in the saliva sample.

13. The apparatus of claim 1 wherein the certain constituent is a cortisol and the reagent is comprised of a chemical composition for changing color in response to a level of the cortisol in the saliva sample.

14. The apparatus of claim 1 wherein the certain constituent is a cholesterol and the reagent is comprised of a chemical composition for changing color in response to a level of the cholesterol in the saliva sample.

15. The apparatus of claim 1 wherein the certain constituent is a salicylate and the reagent is comprised of a chemical composition for changing color in response to a level of the salicylate in the saliva sample.

16. A method for conducting a non-invasive analysis of saliva to determine the presence and the level of a certain constituent carried by the saliva, the method comprising:

providing a base having a visible gauge on a surface of the base, the visible gauge including an interpretation site and visible regions of different colors displayed upon the base adjacent the interpretation site;

providing a lolli-pop-like structure including a stem and a head integrated with the stem, the stem including a finger-grip, and the head including a receptor for the reception of a saliva sample;

providing a reagent carried by one of the head at the receptor and the base at the interpretation site, the reagent being capable of changing color in response to exposure to the certain constituent;

placing a saliva sample on the receptor when the stem is in a first position wherein the head and the stem are away from the base; and

moving the stem to a second position wherein the receptor of the head is placed at the interpretation site, in juxtaposition with the visible gauge, such that upon placement of the stem in the second position, the receptor is juxtaposed with the interpretation site so that any change in color of the reagent in response to exposure of the reagent to the saliva sample is visibly registered with the regions of different colors of the visible gauge for enabling a direct visual matching of the change in color of the reagent with a corresponding color of a visible region of the visible gauge, thereby establishing a directly readable indication of the presence and the level of the certain constituent in the saliva sample.

17. The method of claim 16 wherein the stem is integral with the base and movement of the stem between the first position and the second position is accomplished by bending the stem respectively toward and away from the base.

18. The method of claim 16 wherein the reagent is carried by the head at the receptor, and the method includes exposing the reagent to the saliva sample upon placement of the saliva sample on the receptor.

19. The method of claim 16 wherein the reagent is carried by the base at the interpretation site, and the method includes exposing the reagent to the saliva sample upon moving the stem to the second position, and then moving the stem away from the second position to enable observation of the change in color at the interpretation site.

20. The method of claim 16 wherein the certain constituent is a glucose and the reagent is comprised of a chemical composition which changes color in response to a level of the glucose in the saliva sample.

21. The method of claim 16 wherein the dertain constituent is an alcohol and the reagent is comprised of a chemical composition which changes color in response to a level of the alcohol in the saliva sample.

22. The method of claim 16 wherein the certain constituent is a ketone and the reagent is comprised of a chemical composition which changes color in response to a level of the ketone in the saliva sample.

23. The method of claim 16 wherein the certain constituent is a predetermined drug and the reagent is comprised of a chemical composition which changes color in response to a level of the predetermined drug in the saliva sample.

24. The method of claim 16 wherein the certain constituent is a pregnancy indicator and the reagent is comprised of a chemical composition which changes color in response to the pregnancy indicator in the saliva sample.

25. The method of claim 16 wherein the certain constituent is a cortisol and the reagent is comprised of a chemical composition which changes color in response to a level of the cortisol in the saliva sample.

26. The method of claim 16 wherein the certain constituent is a cholesterol and the reagent is comprised of a chemical composition which changes color in response to a level of the cholesterol in the saliva sample.

27. The method of claim 16 wherein the certain constituent is a salicylate and the reagent is comprised of a chemical composition which changes color in response to a level of the salicylate in the saliva sample.

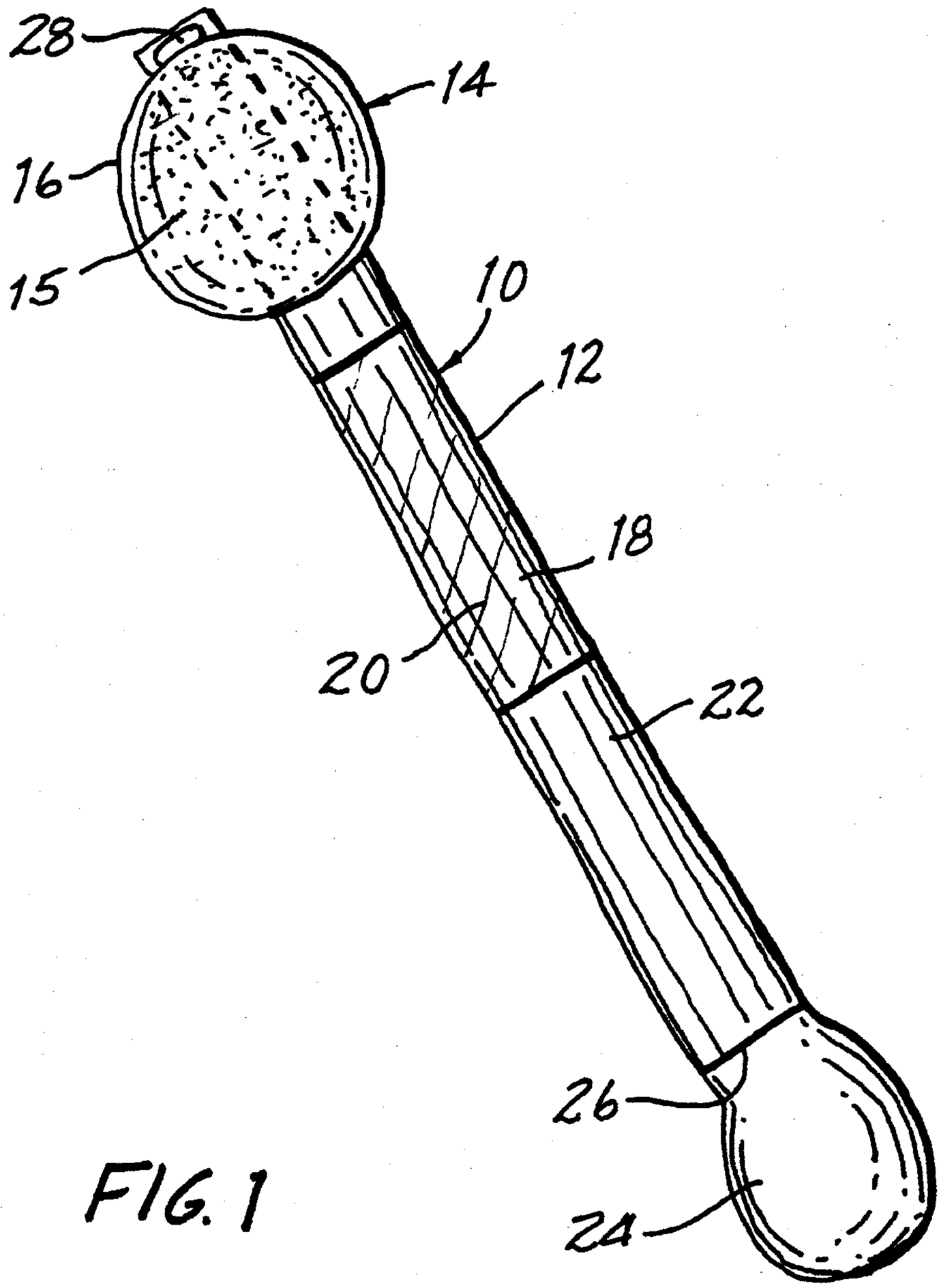


FIG. 1

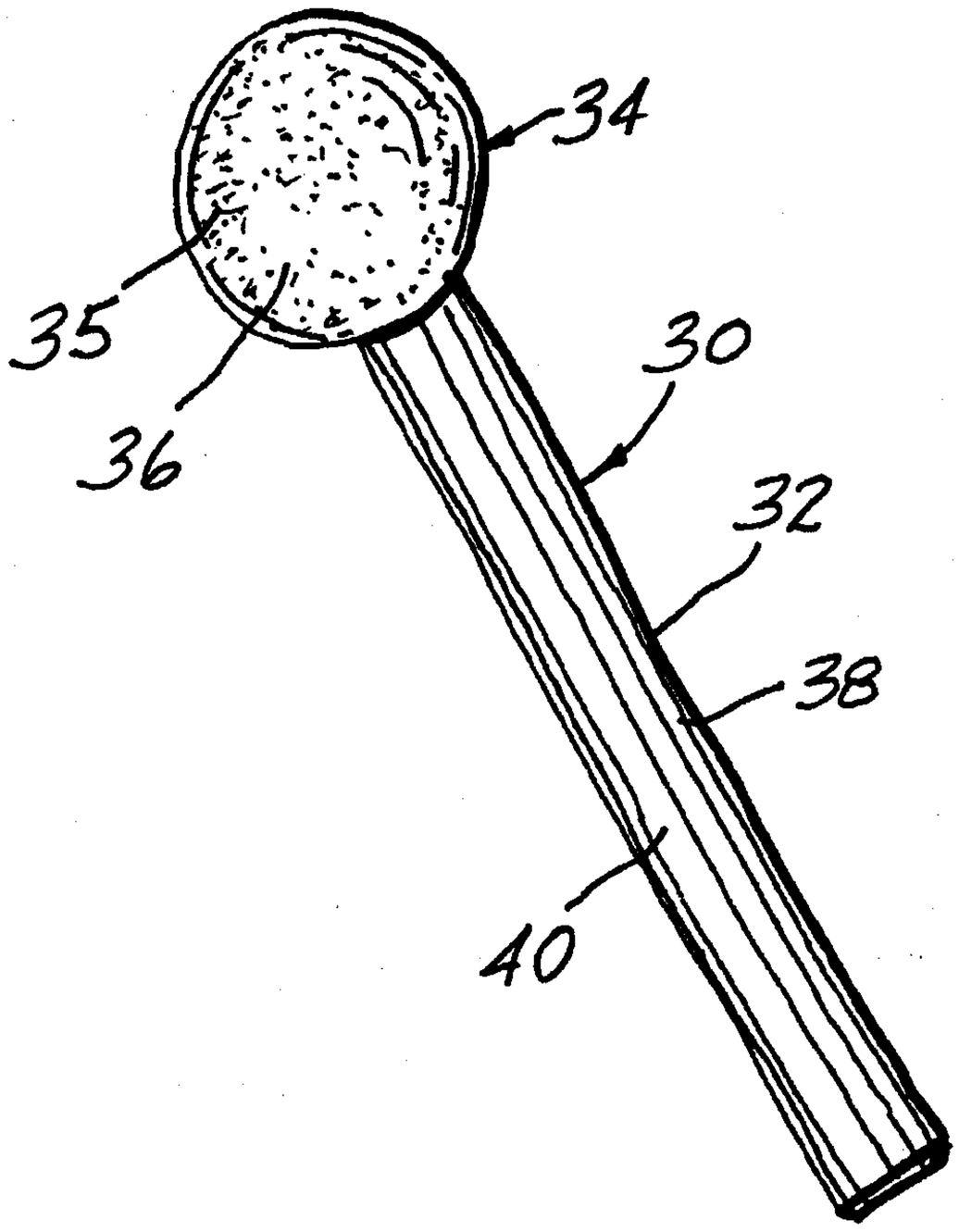


FIG. 2

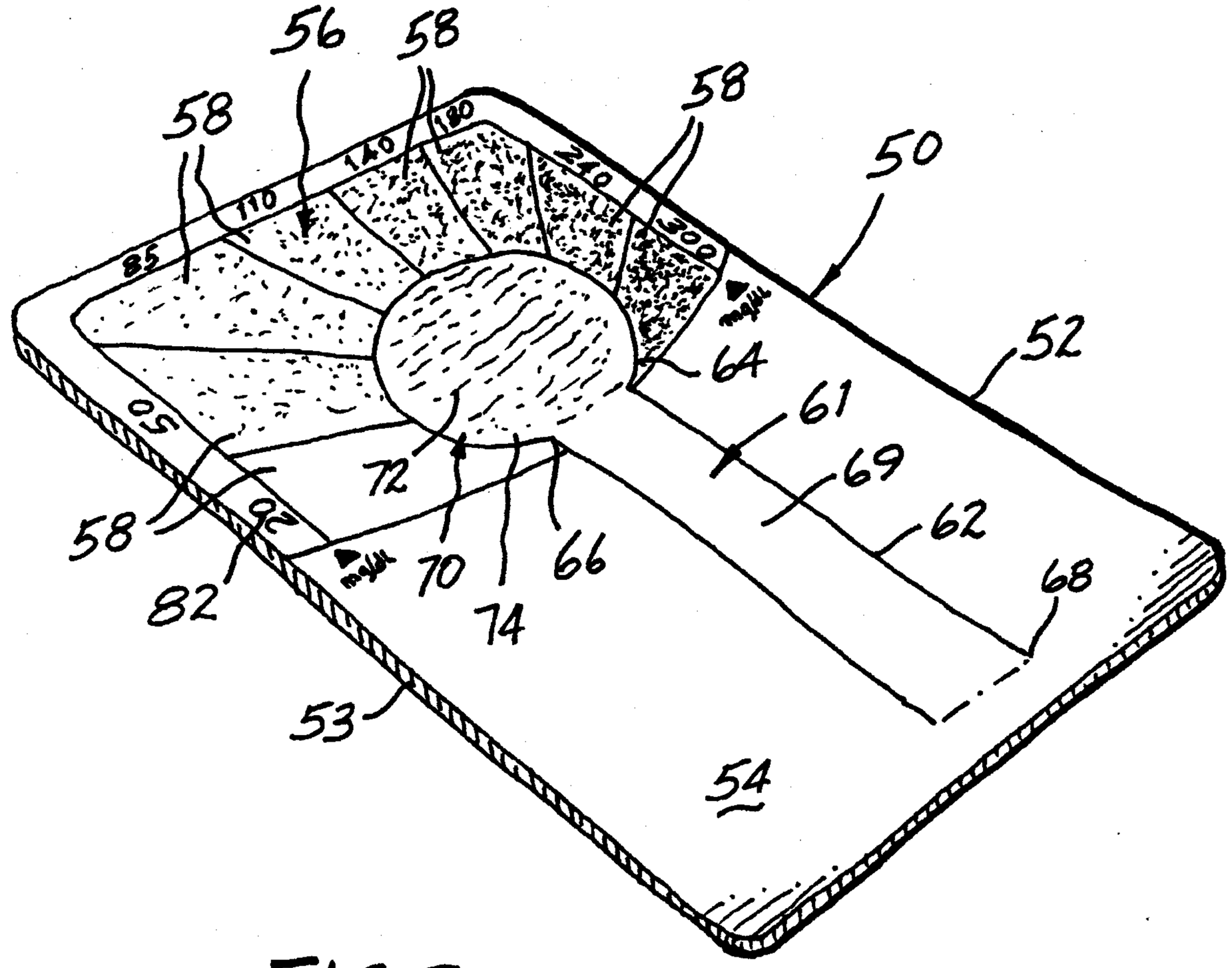
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FIG. 3

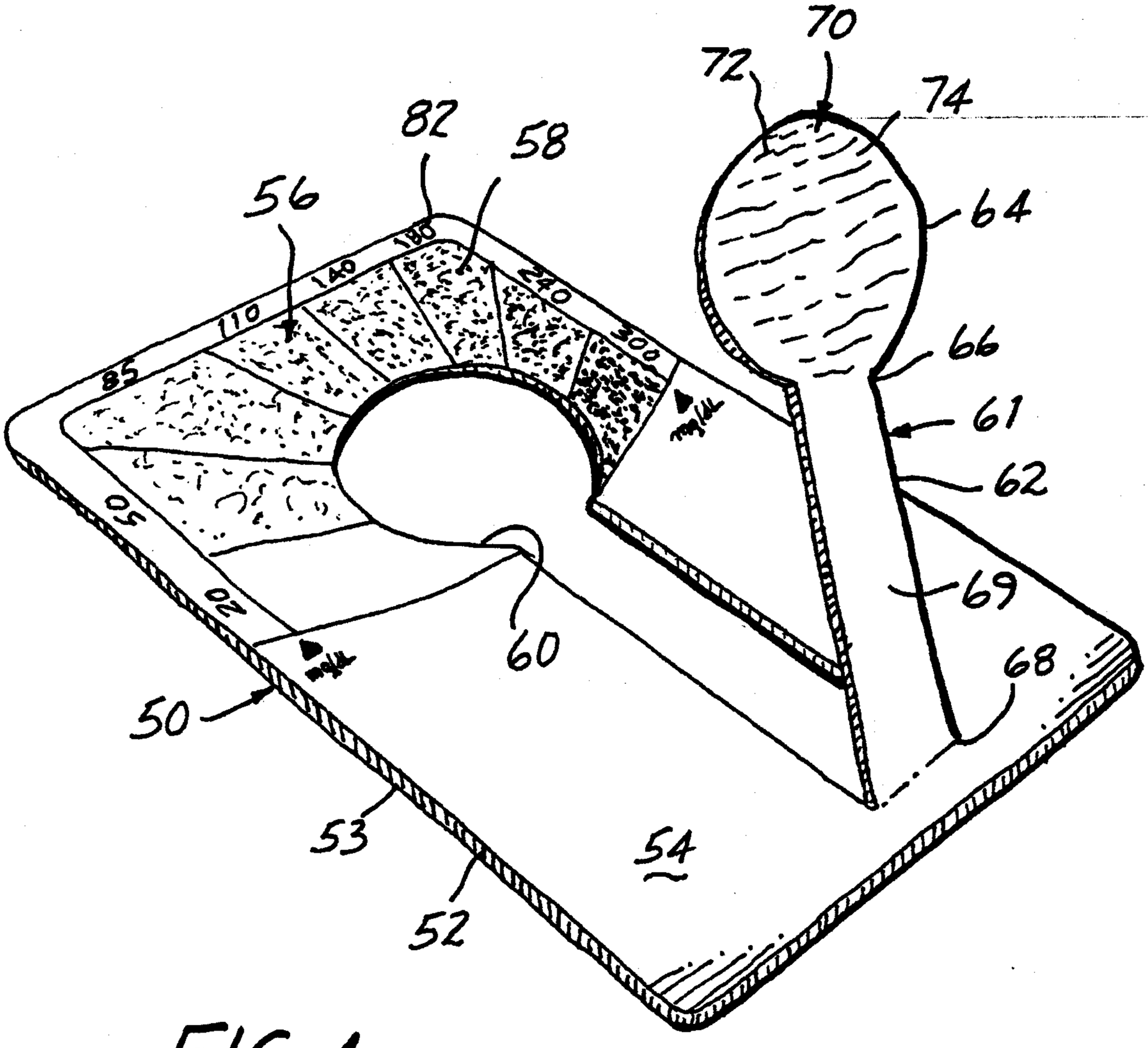
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FIG. 4

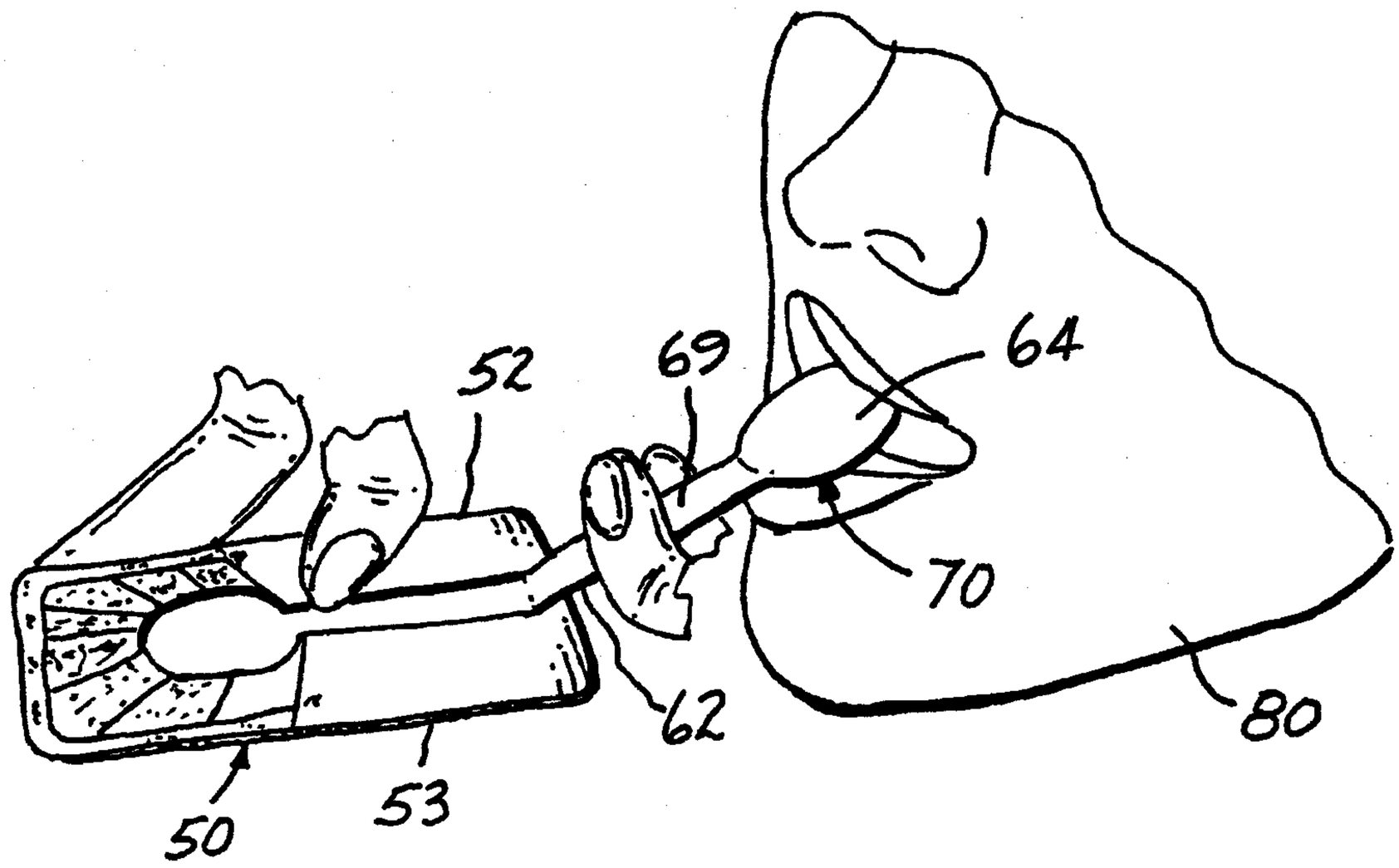


FIG. 5

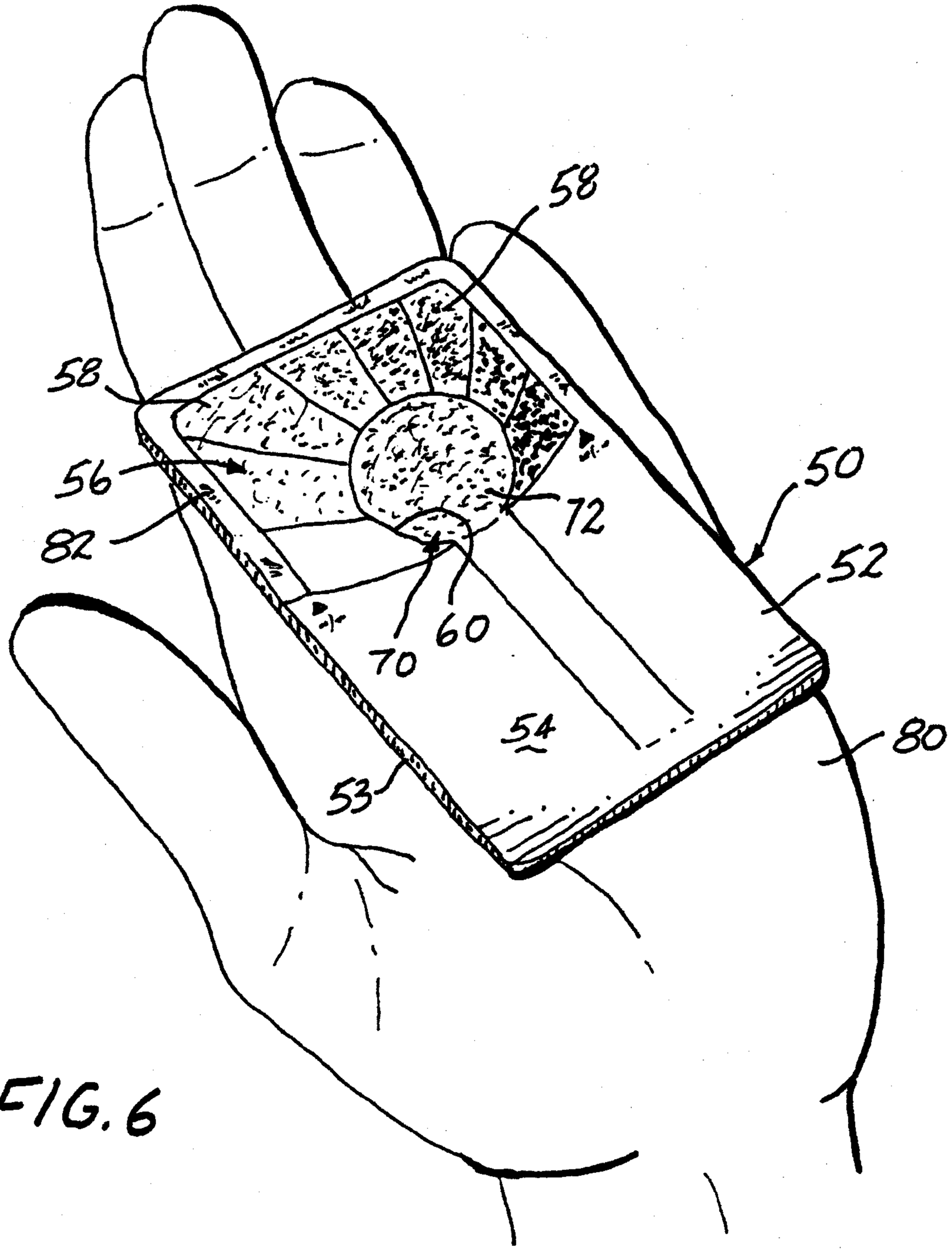


FIG. 6

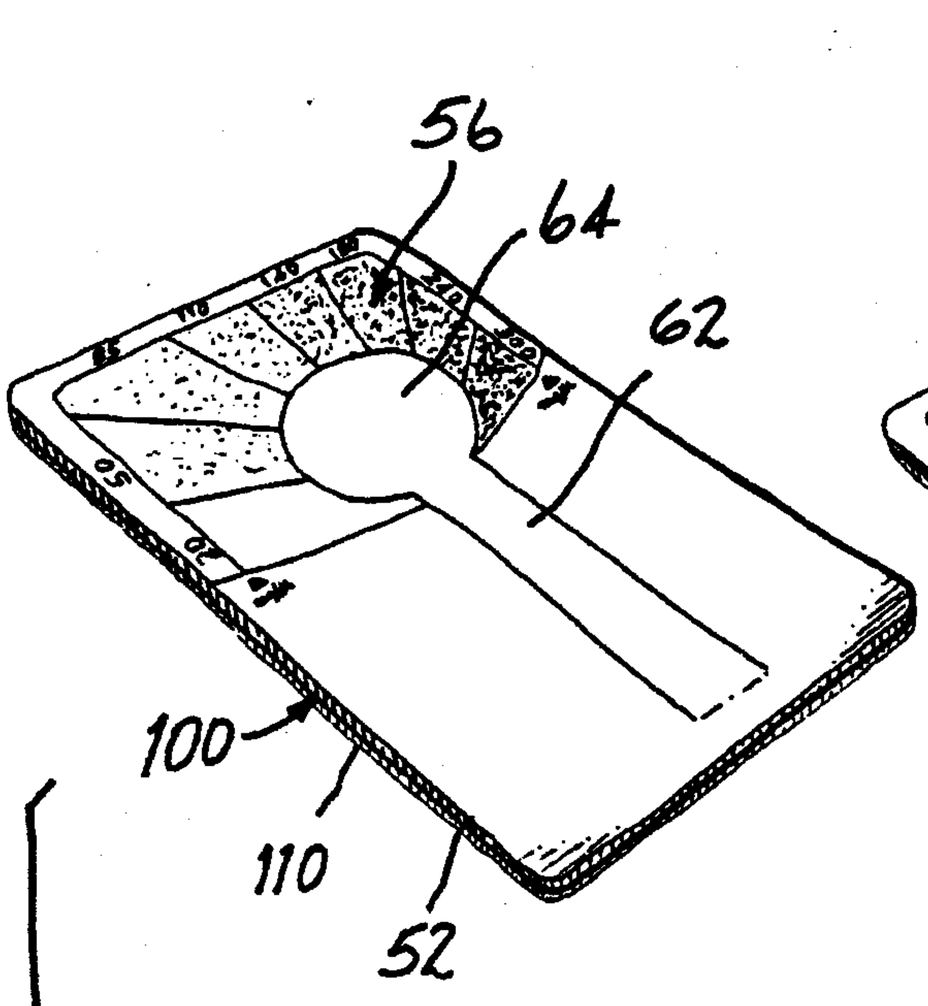


FIG. 7A

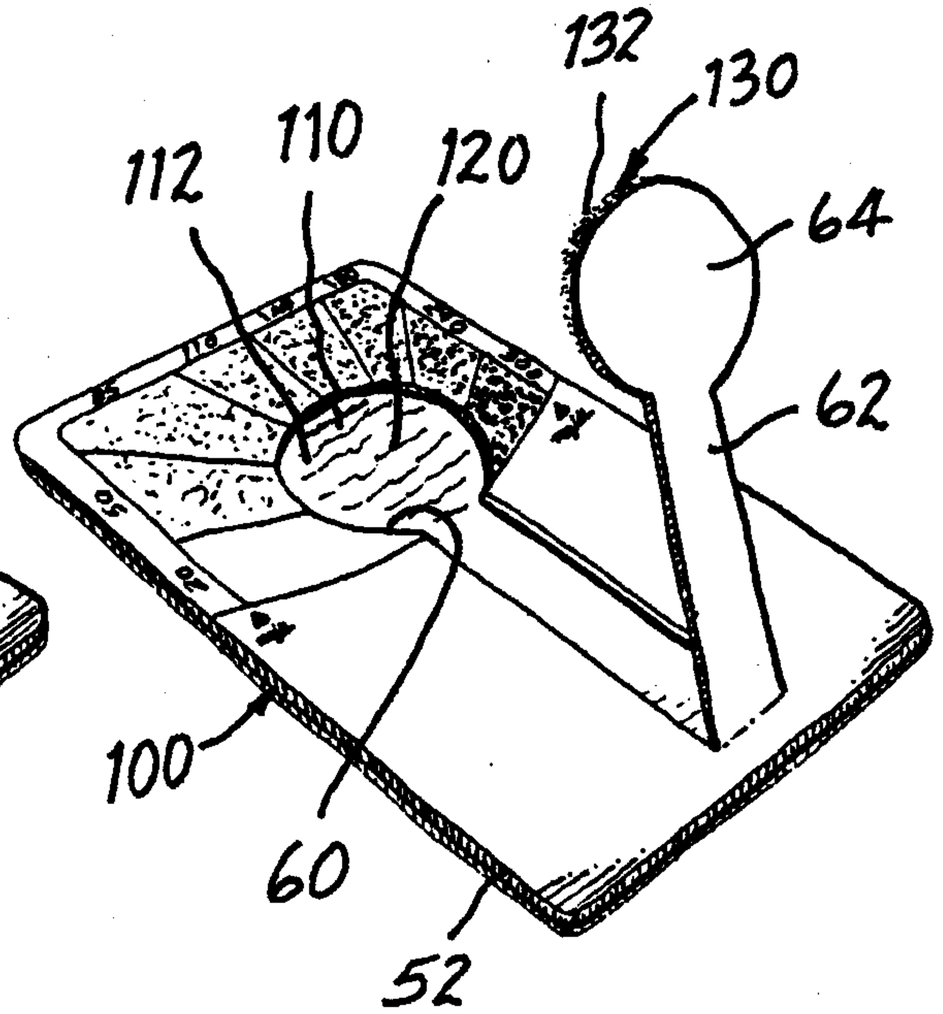


FIG. 7B

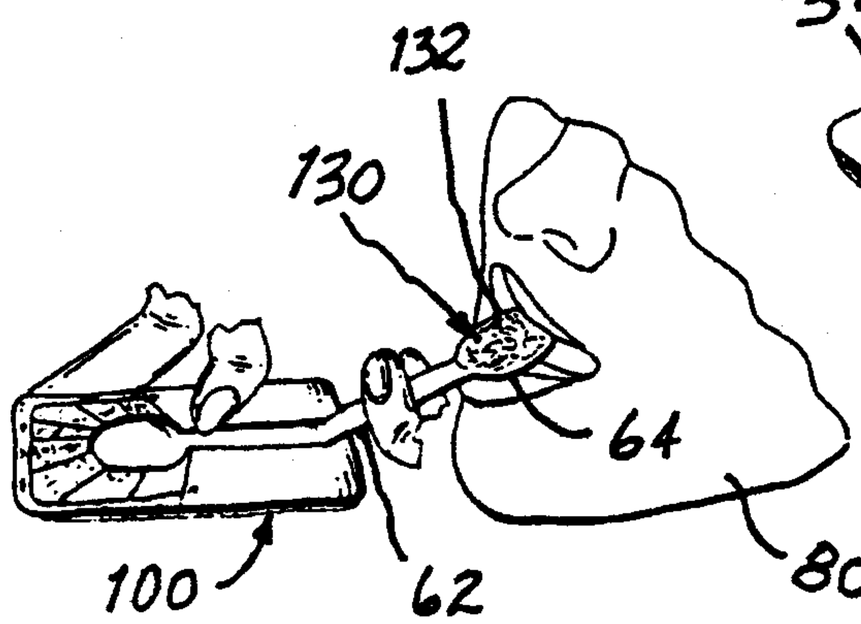


FIG. 7C

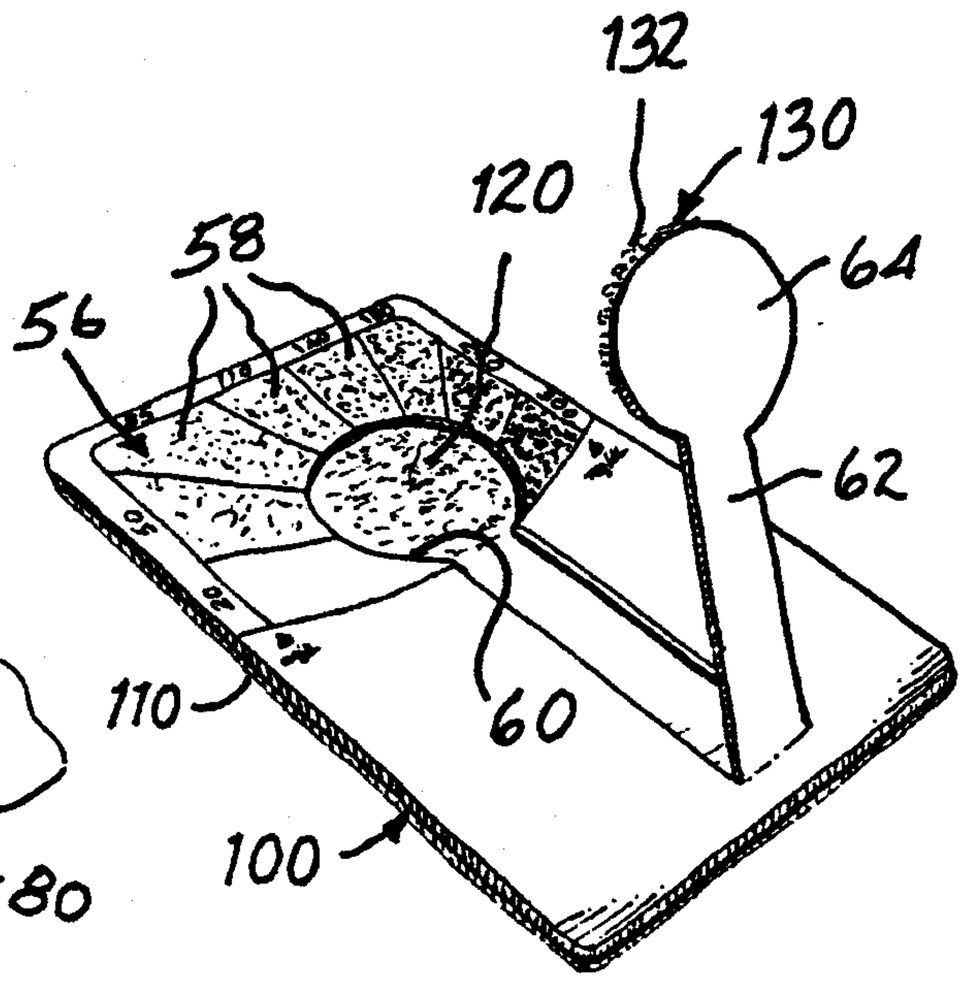


FIG 7D

FIG. 7

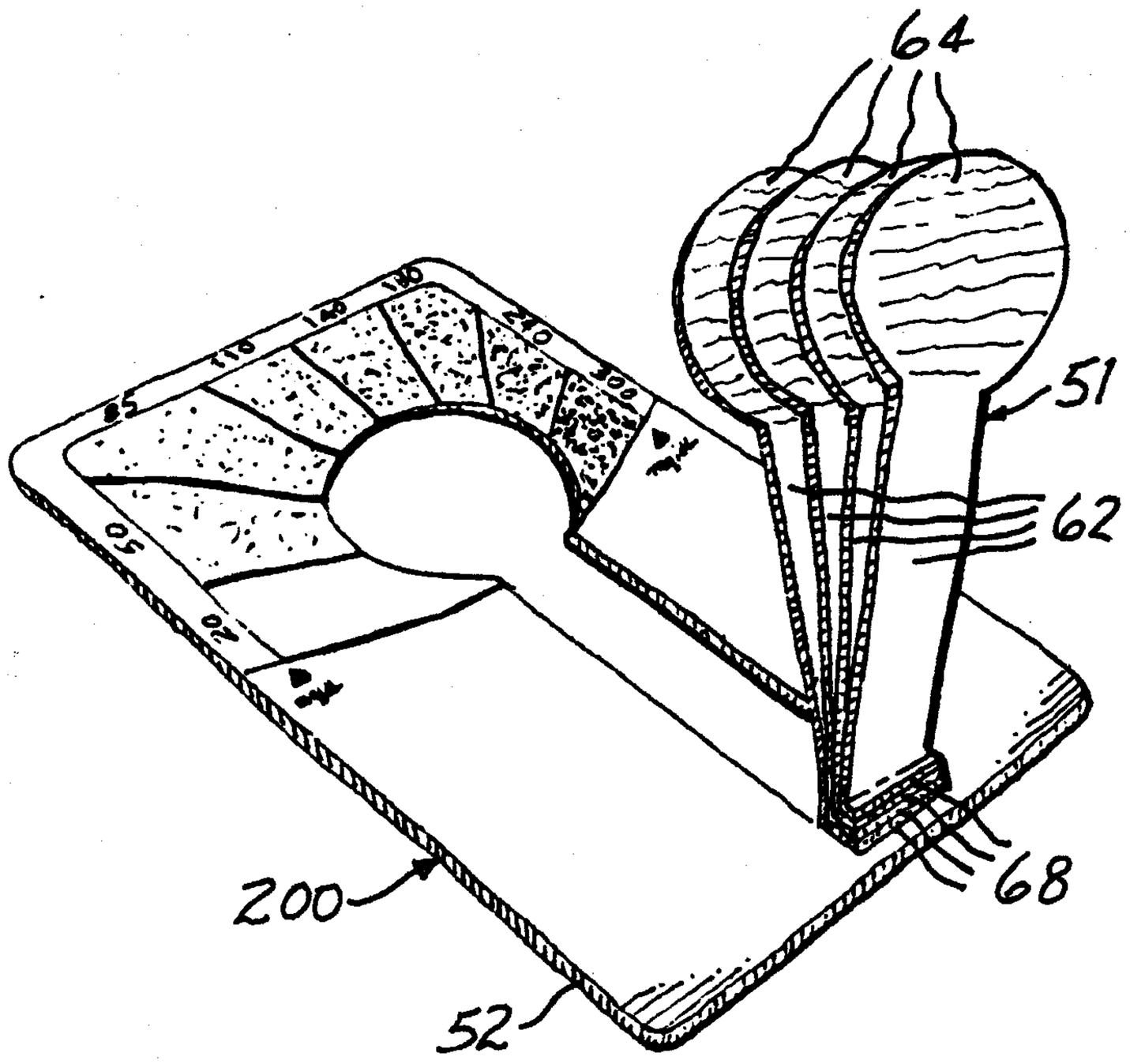


FIG. 8

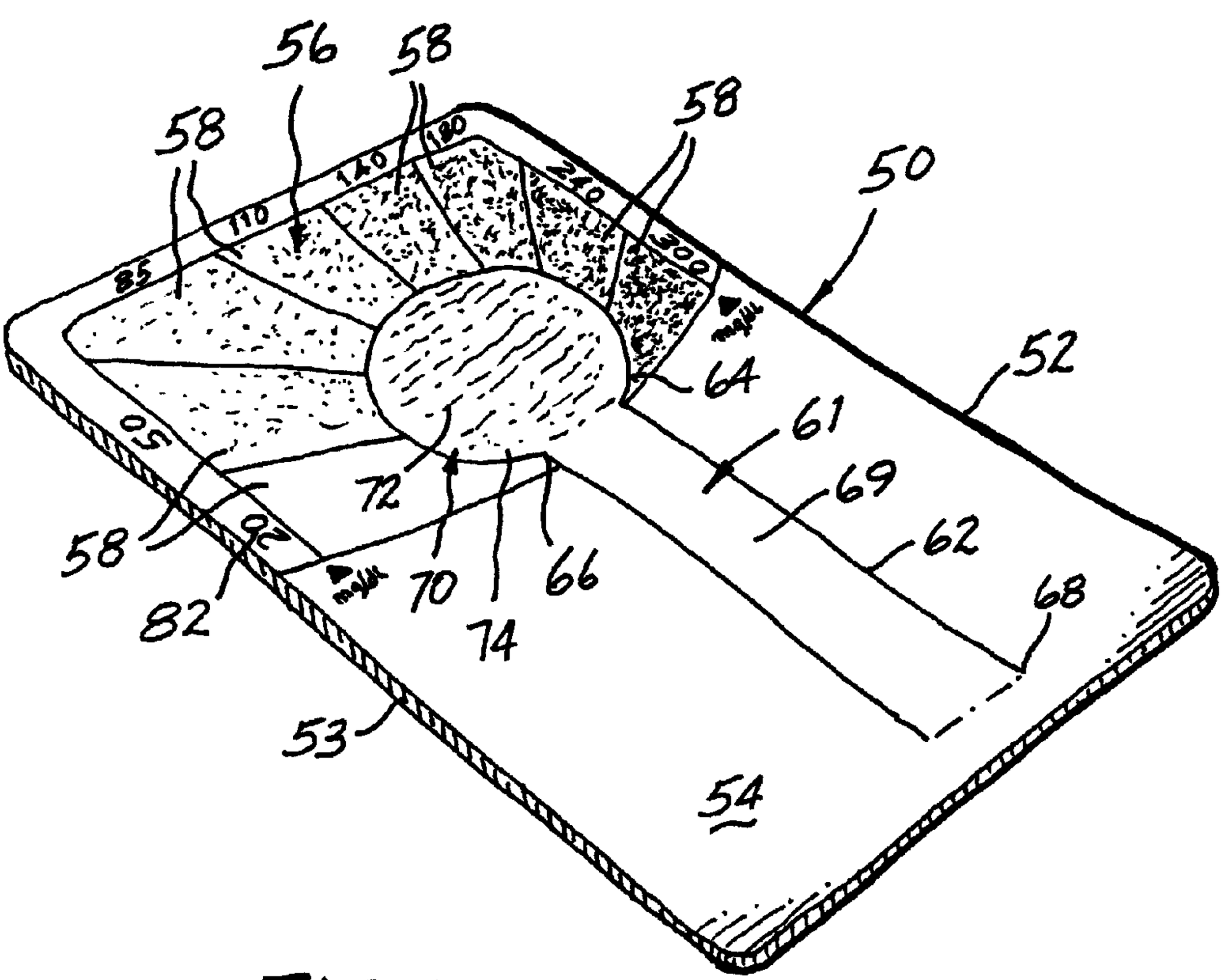
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FIG. 3