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N. B. FURLONG, JR

2,940,448

DISPOSABLE BLOOD-GAS ANALYZER

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Fig-1

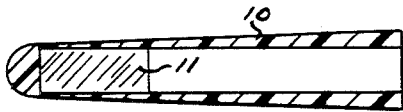
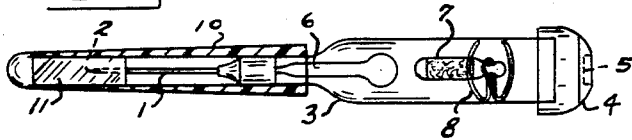


Fig-2



Fig-3

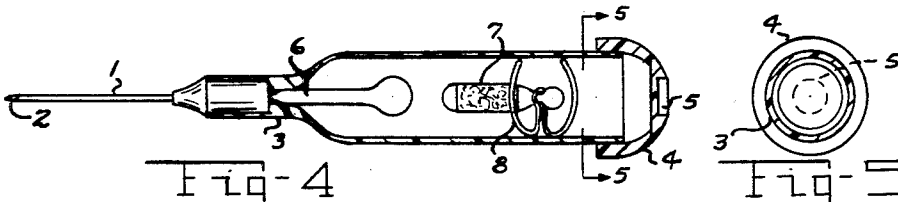


Fig-4

Fig-5

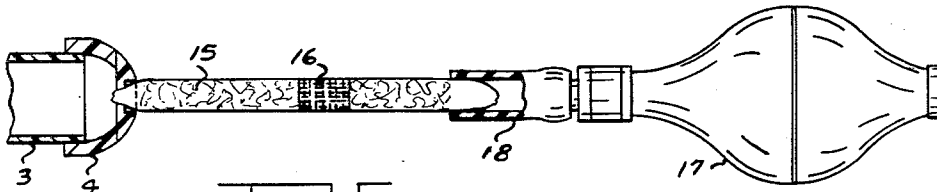


Fig-6

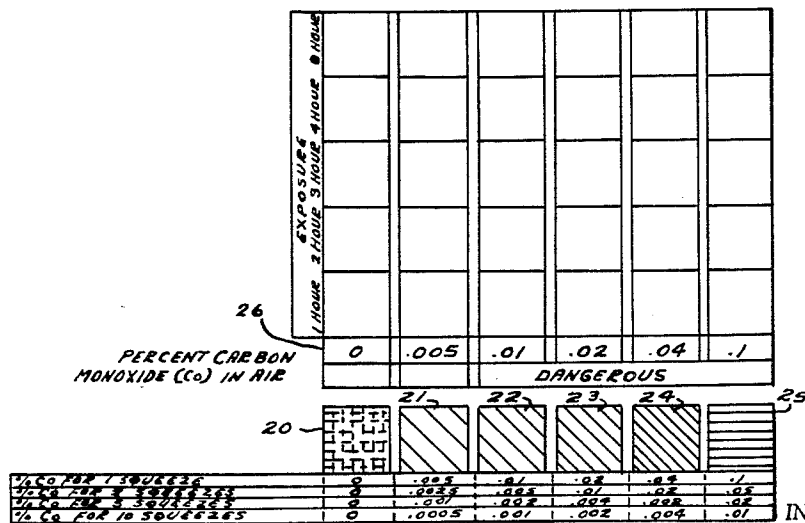


Fig-7

INVENTOR.
 NORMAN B. FURLONG, JR.
 BY *Wade County*
Olson & McCall
 ATTORNEYS

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DISPOSABLE BLOOD-GAS ANALYZER

Norman B. Furlong, Jr., 5241 Cobb Drive, Dayton, Ohio

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10 Claims. (Cl. 128—276)

(Granted under Title 35, U.S. Code (1952), sec. 266)

The invention described herein may be manufactured and used by or for the United States Government for governmental purposes without payment to me of any royalty thereon.

This invention relates to a device for providing a roughly accurate quantitative analysis of the carbon monoxide content in blood.

As a background for understanding the present invention reference is made to "Handbook of Poisons" by Robert H. Dreisbach, published in 1955 by Lange Medical Publications, University Medical Publishers, Los Altos, California.

A brief summary of the invention follows indicating its nature and substance together with a statement of the object of the invention commensurate and consistent with the invention as claimed and also setting out the exact nature, the operation and the essence of the invention complete with proportions and techniques that are necessary for its use. The purpose of the invention also is stipulated. The presentation is adequate for any person who is skilled in the art and science to which the invention pertains, to use it without involving extensive experimentation. The best mode of carrying out the invention is presented by the citing of a specific operative example, inclusive of the preparation and the use of at least one example of the invention.

The object of this invention is to provide a self-contained, inexpensive, disposable device which may be rapidly used by an untrained person with simple manipulation in the making of a reasonably close approximation of a quantitative determination of the carboxy-haemoglobin in a blood sample under standard conditions, after which the device is discarded.

The device does not replace an exact quantitative determination of carbon monoxide absorption into the blood stream, but it is adequate for providing a quick estimate in the hands of a person without skill, beyond observation and judgment in the comparison of shades of color. The device contemplated hereby includes in one unit the factors of sterilization, vein puncture, blood sampling, chemical reaction reagents to release carbon monoxide from the carboxy-haemoglobin molecule and means for making a quantitative colorimetric close determination of the carbon monoxide released from the blood sample taken from the patient.

In the accompanying drawing:

Fig. 1 is a plan view, partly in section, of a hypodermic syringe reaction chamber and a protective covering, which embody the present invention;

Fig. 2 is an enlarged sectional view of the hypodermic needle protecting and sterilizing cap shown in Fig. 1;

Fig. 3 is an elevational view of the open end of the cap shown in Fig. 2;

Fig. 4 is an enlarged sectional view of the hypodermic syringe shown in Fig. 1;

Fig. 5 is a sectional view taken along the line 5—5 of Fig. 4;

Fig. 6 is a plan view, partly in section, of a commer-

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cially available colorimetric analyzing equipment, as applied to the assembly shown in Fig. 4; and

Fig. 7 is a quantitative carbon monoxide colorimetric chart, usable with the color band of the colorimetric tube shown in Fig. 6.

The syringe illustrated in Fig. 1 of the accompanying drawing consists of a hollow steel hypodermic needle 1 with its distal or unattached end 2 sharpened for skin and vein penetration and a reaction chamber 3 hand grasp support for the needle. The proximal or the attached end of the hollow needle 1 is mounted in sealing engagement with and is supported by the extreme end of the flexible neck portion of the tough, flexible plastic reaction chamber 3. The opening through the hypodermic needle 1 is in arrested or blocked communication with the interior of the reaction chamber 3. The thin neck of an evacuated capsule 6 makes a close, axial, sealing slip fit into the neck of the reaction chamber 3 and a loose, spaced penetration into the base of the needle 1.

The reaction chamber 3 is closed and is sealed at its end remote from the needle 1 by being cemented to a cap 4, which is provided with a thin-section tear seal 5 or the like. The hollow glass capsule 6, which is exhausted to a desired degree of vacuum, has a thin walled, shear end positioned within and supported by the base of the needle 1 in the neck of the reaction chamber 3. Reagent containing, additional sealed, thin glass capsules, such as the capsule 7, may also be positioned within the chamber 3. Where desired, the capsules may be secured in place by stainless steel rings, such as the spring steel ring 8 or the like, within the chamber 3. The ring 8 is shown as a continuous wire with spaced ends. The wire is bent to a circular shape with a loop midway between its ends to receive the necked portion of the reagent containing capsule 7 within the loop. The stainless steel ring 8 is adapted for being depressed somewhat, in which state its unattached ends approach each other. The partly depressed, capsule supporting ring 8 is then inserted within the interior of the reaction chamber 3 to a desired position and then released so that the legs of the ring 8 bear outwardly against the inner surface of the reaction chamber 3 and retain the capsule 7 in position. The ring 8 serves the purpose of restricting the undesirable freedom of motion of the capsule it supports so that the capsule is out of contact with other occupants of the interior of the reaction chamber 3. The contents and the number of reagent containers, of which the capsule 7 may be taken as being illustrative, positioned within the reaction chamber 3 may be modified in conformity with requirements, within the contemplation of the present invention.

The capsules 6, 7, etc. within the reaction chamber 3 are made of sufficiently thin walled glass, or similar material, so that they may be fractured or crushed by finger pressure without puncturing the walls of the reaction chamber 3. Illustratively, one of the thin walled glass capsules may contain 100 mg. of powdered dry potassium ferricyanide or a corresponding water solution thereof. A second capsule (not shown) may contain a buffer solution such as 50 mg. of citric acid and 50 mg. of sodium citrate, 10 mg. of powdered saponin, 3 drops of caprylic alcohol and illustratively 1½ to 2 cc. of water. Where desired, the caprylic alcohol may be contained within the evacuated capsule 6, where it minimizes foaming of blood drawn into the capsule 6. The water, or a stable solution, may be left free in the reaction chamber 3 to minimize damage by freezing. Illustratively, the water may be outside of the capsule 7 and the above dry reagents may be positioned within the capsule 7, within the reaction chamber 3.

A hypodermic needle protecting and sterilizing cham-

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ber providing cap or sheath 10 consists of a plastic cylinder or conical member, closed at one end and with its opposite end open and fitting tightly over the needle supporting neck end of the reaction chamber shown in Fig. 1, in sealing relation therewith. The cap or sheath 10 preferably is stiffened against lateral deformation with externally positioned longitudinally extending ribs as indicated in Fig. 3, or the like.

The sheath or cap 10 preferably contains a swab 11 and an antiseptic solution, of which denatured alcohol may be taken as being representative. The hypodermic needle 1 is maintained sterilized by the antiseptic, by which the swab 11 may be saturated. In Fig. 1 of the accompanying drawing, the hypodermic needle, with its antiseptic protective sheath 10, which engages the neck of the reaction chamber 3 in sealing contact therewith, shows the assembly in its sealed condition and suitable for handling and for storage.

Preparatory to the use of the assembly shown in Fig. 1 of the drawing the cap or sheath 10 is withdrawn from its sealing engagement with the neck of the reaction chamber 3 and the cap 10 is tapped against the hand for causing the swab 11 to be removed therefrom. The swab 11 may then be applied along the hypodermic needle 1, for assuring the sterilization thereof. The swab 11 may then be applied to the skin overlying the vein at the inner portion of the elbow bend, which is positioned midway between the extremities of the human arm, or elsewhere, preparatory to causing the penetration of the sharpened tip 2 of the hypodermic needle 1 into the vein for the withdrawal of a blood sample therefrom.

With the tip 2 of the hypodermic needle 1 within the blood filled vein, the flexible neck of the reaction chamber 3 is deflected by the thumb, as the fingers extend around the reaction chamber 3 of the device. The thumb deflection of the flexible neck of the reaction chamber 3 is sufficient to rupture the thin walled seal end of the vacuum capsule 6, thereby opening communication between the interior of the vacuum capsule 6 and the blood filled vein thereby causing the capsule 6 to be filled with a predetermined amount of blood. The hypodermic needle 1 is then withdrawn from the patient and the swab 11 is again used to sterilize the skin wound resulting therefrom.

Where desired, the protective cap 10 may be replaced in sealing engagement with the neck of the reaction chamber 3, thereby increasing the air pressure upon the blood remaining within the hypodermic needle 1 and urging the blood toward the reaction chamber 3 or, if preferred, the sharp tip 2 of the hypodermic needle 1 may be caused to penetrate a rubber or cork stopper or the like, to minimize any blood loss of the sample as taken.

The previously evacuated tube 6, within the reaction chamber 3, is then crushed by finger pressure to release all entrapped blood within the interior of the reaction chamber 3. The capsule 7, and any other capsules which may be contained within the reaction chamber 3, in a similar manner may be ruptured and preferably reduced in particle size by the fingers to release completely their contents into the interior of the reaction chamber 3 and to assure that their contents will be mixed thoroughly with the blood sample within the reaction chamber 3.

The contents of the reaction chamber 3 are then mixed thoroughly by shaking or the like, to release substantially all of the blood carried gas as a vapor, of which carbon monoxide released from carboxy-haemoglobin is taken herein as being representative, within the interior of the reaction chamber 3. At this stage of the development, substantially all of the gas-carrying blood sample is positioned within the reaction chamber 3 and is thoroughly mixed with those reagents which are to act upon the blood sample in releasing its gaseous content therefrom. Within the shaken reaction chamber 3, the cracked glass, by a mechanical scrubbing action, assists in promoting the reaction between the blood and the reagents present, in

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accomplishing the complete extraction of gas from the blood samples. The crushable vacuum capsule 6 has a precision small volume, which illustratively may be $\frac{1}{2}$ cc., which is maintained within a tolerance of about 5%.

The equipment shown in Fig. 6 and the chart shown in Fig. 7 are commercially available. The equipment consists of a carbon monoxide indicator glass tube 15 with a carbon monoxide synthetic yellow reagent colorimetric band 16 intermediate its ends and a slow filling squeeze bulb 17. The squeeze bulb 17 is provided with a resilient tube 18 within the free end of which the less filled end of the tube 15 may be inserted in sealing engagement therewith. The colorimetric tube 15 contains white silica gel plugged in place on the opposite sides of the color band 16. The colorimetric tube 15 has a sturdy mid-section, which is drawn at its opposite ends to glass of sufficiently thinner sections to be frangible, without causing splitting up in the mid-portion of the tube.

In use, both ends of the colorimetric tube 15 are broken open, the less filled end is inserted into the open end of the resilient tube 18 and the opposite end of the tube 15 is caused to penetrate the tear seal 5 of the closure cap 4, in sealing engagement therewith also. The resilience of the wall of the squeeze bulb 17 causes it to dilate against the ambient atmosphere which, upon the removal of the hypodermic needle protecting cap 10, or the removal of the hypodermic needle from a rubber or cork stopper or the like, permits the ambient atmosphere to enter the needle tip 2, to pass along the channel of the needle 1 and to displace any blood within the needle 1 and cause it to flow into the reaction chamber 3 where it is reacted with by the reagents present in causing the liberation of the carbon monoxide gas therefrom.

The continued slow dilation of the squeeze bulb 17 draws the vapor content within the reaction chamber 3 through the colorimetric tube 15, thereby replacing the vapor within the reaction chamber 3 with ambient air which enters the reaction chamber 3 through the channel of the hypodermic needle 1.

The original color of the yellow colorimetric band 16 of the colorimetric tube 15 matches the yellow color of the patch 20, of a patch series numbered 20 to 25, inclusive, shown in Fig. 7. The patch series 20 to 25, inclusive are shaded from the yellow patch 20 through greens 21, 22, 23 and 24 of increasing blue content, to the blue patch 25. The yellow patch 20, as indicated in line 26 thereabove, indicates zero percentage of carbon monoxide in air. The other color patches 21 to 25, inclusive, are color shades assumed by the colorimetric band 16 of the colorimetric tube 15 in the presence within the reaction chamber 3 of sufficient quantities of carbon monoxide in air, in registration with the individual patches and appearing in line 26 thereabove, to cover the range from .005 to .1 percentage of carbon monoxide in air.

Above the row 26 in Fig. 7 of the drawing appears rows and columns of patient exposure effects from carbon monoxide in air. In the first column all of the squares bear the legend "no effects." In the second column, in order from the bottom, there are "no appreciable effects" until the patient has been exposed 8 hours to a concentration of .005 carbon monoxide in air, at which time the effects are "just perceptible." In the third column, in order from bottom for carbon monoxide concentrations in air of .01%, the patient experiences "no appreciable effects" from exposure from one to three hours, inclusive. In the fourth hour effects are "just perceptible" and when exposed for eight hours the patient experiences "appreciable effects." In the fourth column a patient exposed to 0.02% carbon monoxide of air for one hour experiences "no appreciable effects"; when he is exposed for two or three hours he experiences "appreciable effects"; when he is exposed for four hours the patient experiences "headaches and nausea" and the patient exposed to 0.02% carbon monoxide in air for eight hours is in a "dangerous"

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condition. In the fifth column a patient exposed to 0.04% carbon monoxide for one hour experiences "appreciable effects"; for two hours he experiences "headaches and nausea"; and he is in "dangerous" condition when he is exposed from three to eight hours to 0.04% carbon monoxide in air. A patient exposed to 0.1% carbon monoxide in air for one hour experiences "headaches and nausea"; when he is exposed for two hours he is in a "dangerous" condition; and death results from exposure to 0.1% carbon monoxide in air for three hours and beyond.

The data chart represented in Fig. 7 is derived from the Bureau of Standards, as connected with the equipment shown in Fig. 6. The squeeze bulb 17 has a content of about 60 cc. Within the reaction chamber 3, the cracked glass permeated by bubbling air passing through the blood sample in the presence of the described reagents, provides a scrubbing action which assists in the substantially complete extraction of carbon monoxide from the blood sample. The mixing of the blood sample with the reagents within the reaction chamber 3 is continued for a prescribed period of time, of which 30 seconds may be taken as being illustrative, to insure the complete release of carbon monoxide from the blood. The equipment and the procedures disclosed herein may be used for quantitative determinations of materials other than the described procedure, within the conception of the present invention.

It will be understood that modifications may be made in the equipment disclosed, in the reagents cited and in the manipulations described and in departures from the standard conditions of temperature and pressure contemplated hereby, for particular adaptations and uses without departing from the spirit and the scope of the present invention.

I claim:

1. A blood gas analyzer for being used with blood sampling equipment, the analyzer comprising in combination a hollow hypodermic needle, a flexible plastic walled reaction chamber having a neck portion supporting at one end the needle, and a hollow and evacuated frangible capsule provided with one end that is rupturable by the proper deflection of the reaction chamber neck portion and that is mounted in the reaction chamber neck portion in connection with the supported end of the needle and in support of the entire capsule within the chamber and which capsule may be ruptured through the chamber wall for opening the capsule interior to the inside of the reaction chamber for the making of quantitative determinations of the gas content of blood samples drawn through the needle in an amount determined by the degree of evacuation that exists inside of the evacuated capsule into the inside of the reaction chamber of the analyzer.

2. The analyzer defined in the above claim 1 inclusive of a second hollow and frangible capsule with a reagent contained by the second capsule within the reaction chamber and adapted for being released by the rupture of the second capsule by its manipulation through the flexible wall of the reaction chamber in accomplishing the release of an absorbed gas from a blood sample which may be contained within the reaction chamber.

3. A hypodermic syringe comprising the combination of a flexible walled reaction chamber having a neck portion, a hypodermic needle supported at one end by the neck portion of the reaction chamber, a first capsule of tubular glass that is evacuated and that has one frangible end supported in the same reaction chamber neck portion that supports the needle and the body of the glass first capsule positioned within the reaction chamber and the evacuated first tubular glass capsule being adapted for being opened by the deformation for the reaction chamber neck portion and for drawing through the hypodermic needle a predetermined volume of blood to within the first capsule in the reaction chamber, a second capsule

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containing a reagent adapted for accomplishing a reaction with the blood within the reaction chamber upon the rupture of both the first and the second capsules through the flexible wall of the reaction chamber and the reagent reacting with a gas content of the blood sample for causing its release in the vapor phase within the reaction chamber.

4. A hypodermic syringe comprising the combination of a hypodermic needle, a flexible walled reaction chamber having a neck portion supporting the hypodermic needle, a plurality of capsules within the reaction chamber and frangible by finger pressure through the walls of the reaction chamber for the purpose of rupturing the capsules and one of the capsules being evacuated and the evacuated capsule having a frangible end supported by the reaction chamber neck portion and that capsule imparting its evacuated condition to the interior of the needle upon the rupture of the neck of the evacuated capsule and the evacuated capsule being adapted for introducing a predetermined quantity of blood sample within the reaction chamber under ambient standard conditions of temperature and pressure, and a hypodermic needle protecting cap containing a hypodermic needle sterilizing material and a swab for the mechanical application of the sterilizing material to the hypodermic needle.

5. A hypodermic needle assembly consisting of the intercombination of a reaction chamber having a tough flexible wall portion which is deformable by finger pressure and continuing in a neck portion, a hollow needle with a sharpened first end projecting from the reaction chamber and the needle having a second end mounted in and supported by the reaction chamber neck portion and the needle mounted and available for opening into the interior of the reaction chamber, an evacuated capsule positioned within the reaction chamber with one attached end mounted in the reaction chamber neck portion and rupturable from external pressure applied thereto for the purpose of applying its evacuated condition to the attached end of the hollow needle on the rupturing of the evacuated capsule, a reagent containing capsule within the reaction chamber and adapted for being ruptured through the wall thereof for the purpose of releasing the contents of the reagent containing capsule into the interior of the reaction chamber to mix with the contents of the evacuated capsule on the rupture thereof, a hypodermic needle cap protectively housing the distal end of the hypodermic needle and engaging in sealing relation with a portion of the reaction chamber, a swab within the hypodermic needle protective cap, and an antiseptic within the hypodermic needle protecting cap for the purpose of sterilizing the needle.

6. A hypodermic needle assembly for making approximations of carbon monoxide in carboxy-haemoglobin of a blood sample comprising the combination of a hypodermic needle, a hollow flexible reaction chamber with a deformable neck and wall portions of which the neck portion supports an end of the hypodermic needle, an evacuated capsule within the reaction chamber and with one frangible end connected into the supported end of the hollow hypodermic needle such that the frangible end is adapted for being ruptured by finger manipulations from the outside of the reaction chamber for the purpose of drawing a predetermined quantity of blood sample into the reaction chamber under standard conditions of temperature and pressure, a hypodermic needle protecting and sterilizing cap for receiving the hypodermic needle within the cap in removable sealing relation with the reaction chamber, a closure cap having a tear seal closing the reaction chamber at the end remote from the hypodermic needle and the tear seal of which closure cap being adapted for being perforated by a commercially available carbon monoxide colorimetric tube adapted for being opened at both ends and for indicating quantitatively the carbon monoxide content of the blood

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sample within the reaction chamber upon the withdrawal of the vapor within the reaction chamber through the colorimetric tube.

7. A hypodermic needle assembly for the making of carbon monoxide determinations in carboxy-haemoglobin of a blood sample comprising the combination of a hollow hypodermic needle, a hollow and flexible reaction chamber provided with a neck portion that grips a proximal end of the hypodermic needle, an evacuated first capsule supported within the reaction chamber by the reaction chamber neck portion and the evacuated capsule terminating at its supported end in a frangible tip which extends sufficiently into the attached end of the hypodermic needle to cause the frangible tip to rupture on the lateral displacement of the portion of the evacuated capsule within the reaction chamber, a thin walled glass second capsule containing 100 milligrams of powdered dry potassium ferricyanide and positioned within the reaction chamber, a third capsule containing 50 milligrams of citric acid and 50 milligrams of sodium citrate and 10 milligrams of powdered saponin and 3 drops of caprylic alcohol and from 1½ to 2 cubic centimeters of water and being positioned within the reaction chamber such that on the combination of the contents of the reaction chamber with a sample of carboxy-haemoglobin blood the combination will produce a color which is indicative quantitatively of the carbon monoxide content of the blood sample.

8. The assembly defined in the above claim 7 wherein the evacuated capsule, rather than the third capsule contains the three drops of caprylic alcohol for minimizing the foaming of blood entering the reaction chamber.

9. The assembly defined in the above claim 7 wherein the interiors of the capsules are substantially dry and the water is positioned inside of the reaction chamber and outside of the capsules to minimize damage by freezing.

10. A syringe comprising a hollow steel hypodermic

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needle sharpened at an unattached end for skin and vein penetration and having an attached end for needle manipulation, a hollow and deformable reaction chamber made of a tough and flexible plastic and the reaction chamber having at one end a flexible neck portion in which the attached end of the needle is mounted in arrested and block communication with the interior of the reaction chamber and at the end of the reaction chamber remote from the needle mounting neck portion the reaction chamber is provided with a thin section seal through which access into the interior of the reaction chamber is available, an evacuated capsule provided with a thin and frangible neck portion making a slip fit into the neck of the reaction chamber and penetrating into the attached base of the needle and the reaction chamber neck portion supporting the evacuated capsule which extends into the interior of the reaction chamber such that on a sufficient deformation of the reaction chamber neck portion the interior of the evacuated capsule is caused to be applied to the needle, and reagent containing frangible capsule means within the reaction chamber and rupturable through the chamber wall.

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