United States Patent

Hanafin

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[54] BLOOD PRESSURE CUFF WITH CALIBRATED HOLDING MEANS

[72] Inventor: **Paul M. Hanafin,** 240 Readington Road, Somerville, N.J. 08876

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[52] **U.S. Cl.** .....**128/2.05 C,** 128/327

[51] **Int. Cl.** **A61b 5/02**

[58] **Field of Search** .....128/2.05 A, 2.05 C, 2.05 G, 128/2.05 M, 2.05 Q, 2.05 R, 2.05 V, 327

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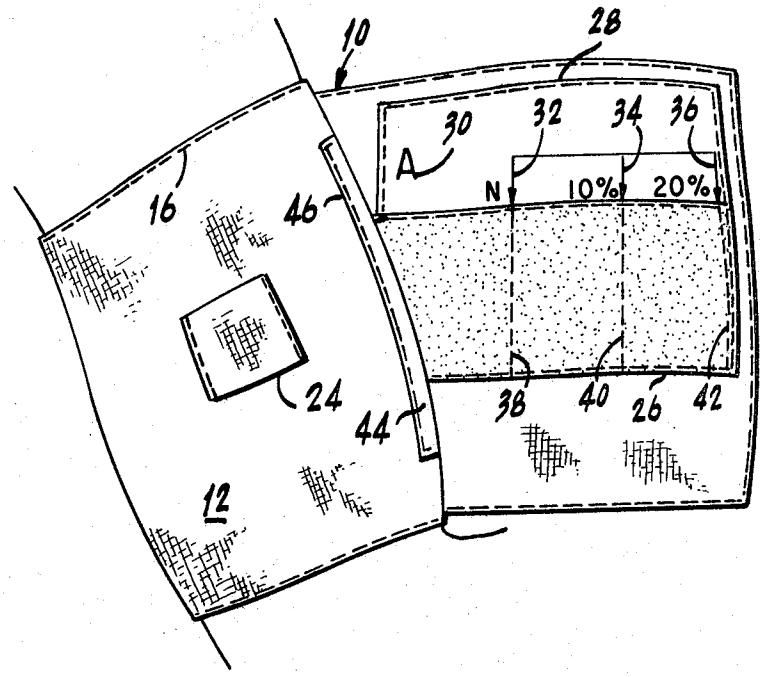
Primary Examiner—William E. Kamm
Attorney—Sperry and Zoda

[57] **ABSTRACT**

A blood pressure cuff including a visual indication of the limit of assured accuracy in the blood pressure recording. The point of the cuff closure is marked to show said limit, the indicia being located in reference to the ratio which the diameter of the limb encircled by the cuff bears to the width of the occluding bladder. The markings assure acceptance (despite differences of opinion in the scientific community) by the major recognized associations concerned with the establishment of cuff design standards.

The cuff minimizes disregard of the indicia and the consequent taking of an inaccurate recording, by incorporation of a "fail-safe" connection between the mating cuff ends. The connecting means loses holding power and fails to maintain closure of the cuff when gas pressure is applied to the bladder in the normal fashion, if the ratio of limb diameter to bladder width exceeds known standards.

10 Claims, 8 Drawing Figures



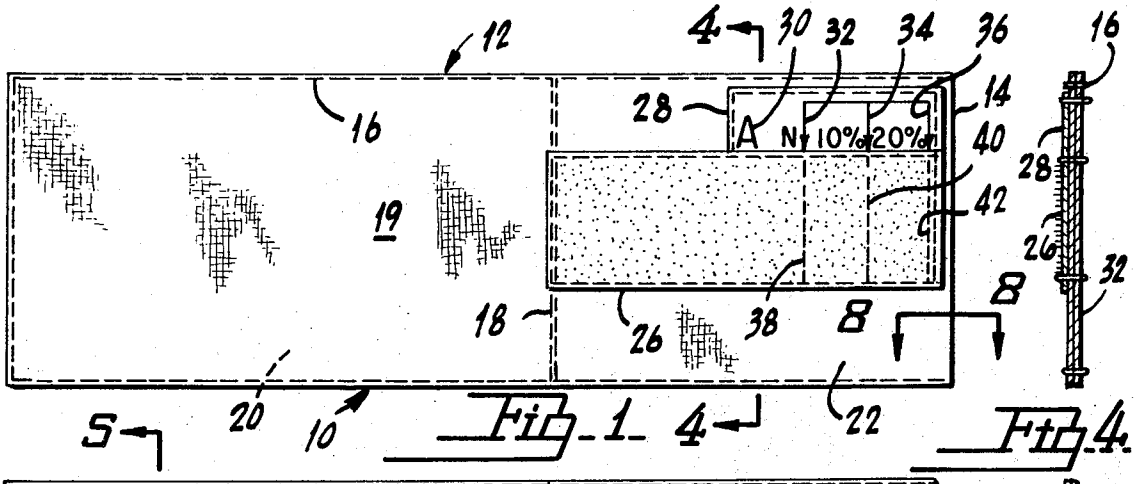


Fig. 1

Fig. 4

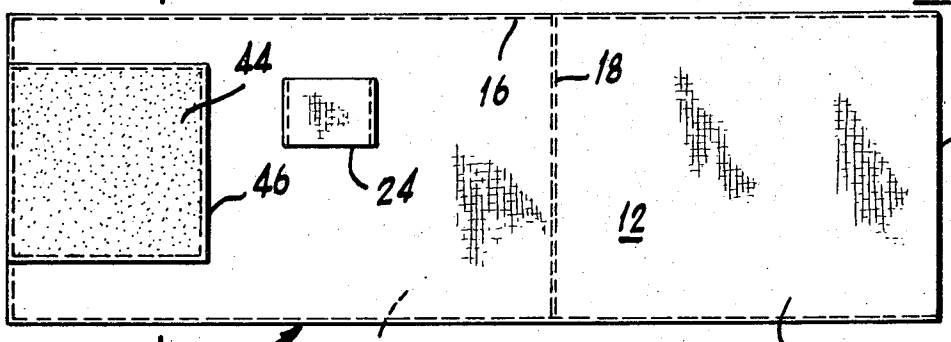


Fig. 2

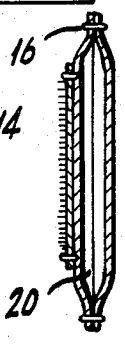


Fig. 5

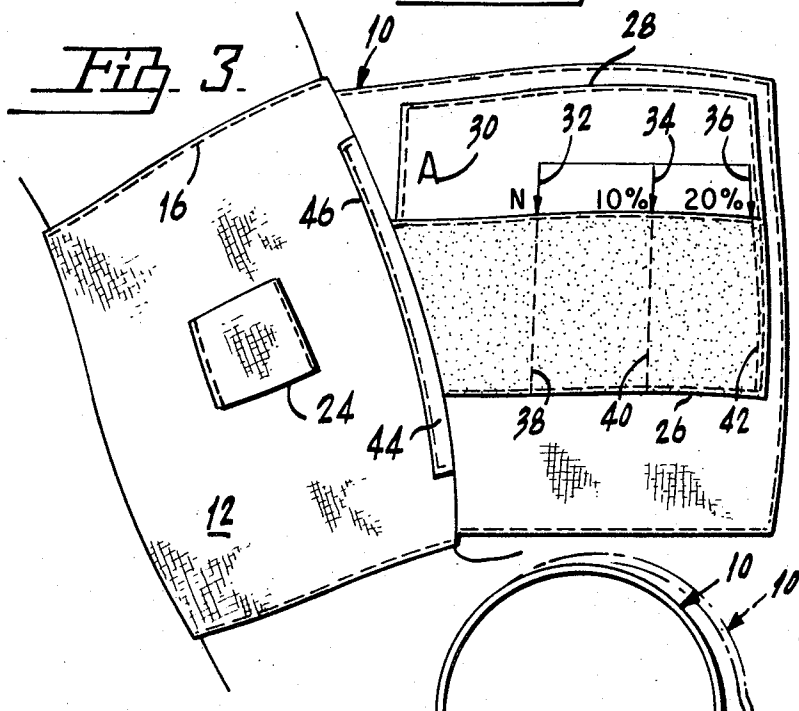


Fig. 3

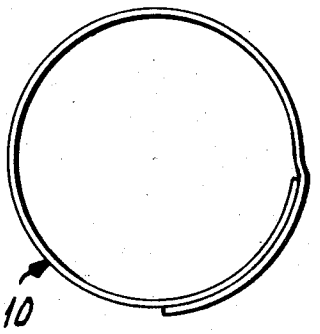


Fig. 6

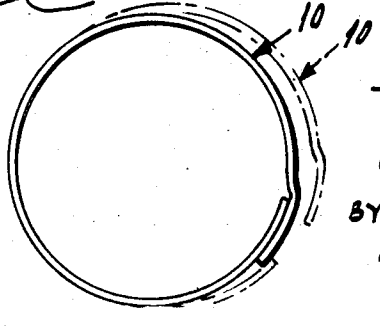


Fig. 7

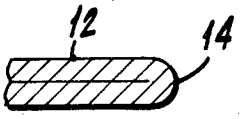


Fig. 8

INVENTOR
PAUL M. HANAFIN
BY Avery and Soda
ATTORNEYS

BLOOD PRESSURE CUFF WITH CALIBRATED HOLDING MEANS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention pertains generally to the art of diagnostics, in particular the diagnosis of cardiac conditions.

In a more particular sense, the invention is concerned with the provision of an improved blood pressure cuff to be utilized as a part of a diagnostic device or instrument.

The invention is primarily concerned with embodying, in a blood pressure cuff, a means of marking thereon a limit of assured accuracy, using as a point of reference the ratio of limb diameter to occluding bladder width. Further incorporated in the invention is a "fail-safe" feature, such that a disregard of the indicia of the limit of assured accuracy, whether intentional or inadvertent, will produce a loss of holding power in the cuff with resultant opening thereof as soon maximum gas pressure is applied in the normal method employed in blood pressure determination.

2. Description of the Prior Art

The prior art indicates a recognition of the criticality of occluding bladder width, and suggestion has been made that there be certain ratios of bladder width to limb diameter. And, there has also been discussion along with efforts to achieve standardization, with respect to the extent to which the bladder should encircle the limb, in order to assure as much as possible the taking of an accurate recording.

Von Rechlinghausen, in 1901 suggested that the width of the occluding cuff was of critical importance since a cuff too narrow gave generally high blood pressure values. His recommendations that a minimum bladder width of 12 cm. on the adult upper arm have been carried forward to the present time. Hill and McQueen in 1916 tended to explain the width requirement as necessary for occlusion of venous outlets.

Medical standards entitled: "Standardization of blood pressure readings " were promulgated by the American Heart Association, Inc. in 1939, based on the joint recommendations of the American Heart Association and the Cardiac Society of Great Britain and Ireland. These were the first universally accepted domestic standards on cuff sizing. Bladder specifications set forth in these standards resulted in a 12 or 13 cm. width and a 23–24 cm. length on the adult cuff. The requirement of a 50 percent bladder encirclement of the arm was noted and the suggestion to center the bladder over the artery to be measured was made.

In 1951, and again in 1967, these recommendations were rewritten by the American Heart Association in a document entitled: "Recommendation for Human Blood Pressure Determination by Sphymomanometer." Bladder requirements were changed to include a provision that the inflation bag should, roughly speaking, be 20 percent wider than the diameter of the arm or thigh on which it is to be used. Specific widths for other than adult size cuffs were given. A 50 percent bladder limb encirclement was stated as desirable and the notation was made that some authorities believe that any risk of misapplication should be obviated by use of a bag that nearly or completely encircles the limb.

It should be noted that research articles on blood pressure universally include the 1939, 1951 and 1967 recommendations as standard. Despite the 1951 and 1967 recommendations on the importance of cuff widths, however, no one has to my knowledge provided a cuff which indicates the recommended ratio or in any way indicates conformance to ratio recommendations. The closest approach to ratio is conformance based on an article at Edinburgh University, Scotland which attempted to assign plus or minus values for various size arms. A cuff conforming to these specifications was advertised and marketed in England in the late 1950's. Current literature, since 1960, does not support a numerical value based on arm size with adult cuffs and the scientific reason for variations due to cuff width-arm diameter ratios is open to many interpretations. Further, a suggestion on a fail-safe ratio has been lacking in the literature.

There is also a body of clinical and scientific medical evidence to the effect that if a bladder completely or nearly encircles a limb with a width of 15, 14 or 12 cm. (depending on the author) the true interarterial pressure is most nearly approximated by the indirect blood pressure recording method.

Karvonen in 1953 and the World Health Organization recommendations took this position. However, it is interesting to note that European authorities and manufacturers have tended to reduce bladder length from 35 to 40 cm. toward the historic British and American standards of 23 cm. length. Recently Simpson in 1965 and King in 1966 have attempted to prove the validity of longer length of bladder with nearly complete encirclement.

The studies of Moss in 1962 did much to improve accuracy in child cuff sizing in the ranges of infant, child and newborn cuff sizes. His conclusion was that cuff width to arm diameter was of prime importance over other factors. However, his recommendations resulted in cuffs in each size which nearly encircled the limb within fixed bladder widths and conformed to the American Heart Association ratio recommendations.

It will thus be seen that different views are held by scientific authorities, with respect to the ratio which cuff width should bear to limb diameter, and with respect to the extent of limb encirclement by the occluding bladder. It is well settled, however, that in point of actual fact the width of the bladder is significant, the extent of encirclement is significant also, and the ratio of the width of the cuff to the diameter of the encircled limb is, indeed, also of significant and undoubtedly even critical importance.

Yet, to my knowledge, no cuff has been designed so far that will assure the taking of an accurate recording if visual indicia thereupon are respected by the user, and which will further assure failure to maintain cuff closure if the user goes beyond any limits recognized by competent scientific authority, even though said authority may differ from other schools of thought bearing upon the subject.

SUMMARY OF THE INVENTION

Summarized briefly, the invention comprises a blood pressure cuff which, in the first place, can be made in any of certain main sizes, such as, for example, adult, child, and obese. In each of these main categories, the

cuff incorporates the conventional inflation bladder, means for connection of the bladder to a source of air under pressure, and means for associating the same with a conventional sphygmomanometer. The invention resides in the provision of indicia indicating (whether the cuff be of the adult, obese or child size) whether or not the applied cuff is within limits of assured accuracy as determined by recognized bodies of scientific opinion.

The invention further incorporates a fail-safe connection between the overlapping end portions of the applied cuff, such that the connection means will fail upon application of air pressure, if its use is attempted beyond a predetermined tolerance value as regards the ratio of arm diameter to cuff width.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** is an elevational view of an opened blood pressure cuff according to the present invention;

FIG. **2** is an elevational view of the cuff, showing the other face thereof;

FIG. **3** is a perspective view, showing the cuff during its application to an arm;

FIG. **4** is a transverse sectional view substantially on line **4**—**4** of FIG. **1**;

FIG. **5** is a transverse sectional view substantially on line **5**—**5** of FIG. **2**;

FIG **6** is a somewhat diagramatic edge view of the cuff, as it appears when properly applied and within safe limits;

FIG. **7** is a view like FIG. **6**, showing the cuff applied under conditions exceeding the reasonable excess value above recommended limits, the dotted lines showing the cuff opening to prevent use under these conditions; and

FIG. **8** is an enlarged detailed sectional view substantially on line **8**—**8** of FIG. **1**

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. **1** and **2**, the illustrated cuff **10** comprises a length of fabric **12** folded upon itself along a transverse fold line **14**, which thus defines one end of the cuff. A line of stitching **16** extends along the longitudinal edges and the registered ends of the material, whereby the cuff comprises an elongated, rectangular body of double thickness adapted to be wrapped about the patient's arm A.

A transverse line of stitching **18** is extended between the opposite longitudinal edges of the body **19** defined by the superimposed portions of the fabric, and defines, between the line of stitching **18** and the end of the body more remote therefrom, a hollow, rectangular space which is or accepts an occluding bladder **20**.

It will be noted at this point that the term "occluding bladder" as used herein is so used in the broad sense. Quite possibly, in some blood pressure cuffs constructed according to the present invention, the bladder **20** might itself receive an inflation bag, not shown in the present drawings. Or, in other forms, the bladder **20** might itself be inflated. It is sufficient to note for the purposes of the present application that the term "bladder" as used in the description and claims of this application is intended to refer to a portion of the cuff which may itself, or by the provision of an insertable bag, be connectable to a source of air under pressure for the purpose of inflating the same during the normal use of the device.

At the opposite side of the line of stitching **18**, that is, the portion of the device lying between said line of stitching and fold line **14**, the cuff has a non-inflatable area **22**.

On what might be termed the outer side of the cuff, using the term in the sense of the side that is exteriorly disposed when the cuff is applied to the limb, there is provided an aneroid holder **24**, in the form of a small, rectangular piece of fabric open at its top and bottom, and stitched to the outer side of the bladder **20** along the opposite side edges of the holder.

Connecting means is embodied in the cuff, for the purpose of separably joining the opposite end portions of the cuff in an overlapped relation, when the cuff is applied to the patient's limb. The connecting means in the illustrated example includes, on the inner face of the cuff, a pad **26**, located substantially midway between and in parallel relation to the opposite longitudinal edges of the body, and extending almost the full distance from the line of stitching **18** to the fold line **14**. Pad **26** is in juxtaposition to a label **28**, which is also stitched to the area **22** of the cuff body, and which is provided at one end with an indicium **30** comprising a main size indicator. By this is meant an indication or marking of the general, overall size of the cuff. As previously noted in this application, the cuff would likely be made in three mainly used sizes in a typical commercial embodiment. This would be a size for adults, a size for children, and a size for obese individuals. However, other accepted sizes are also envisioned, as for example sizes for infants and the newborn, sizes for application to the thigh, etc. In the illustrated example, the adult size, denoted by the indicium "A" is illustrated by way of an example. Regardless of the size of the cuff, in every instance it would be provided with other indicia **32**, **34**, **36**, having an important purpose in carrying out the inventive concept, namely, the provision of a visual reference whereby the user may ascertain whether the cuff application is within the limits of assured accuracy as regards the taking of a blood pressure recording.

The indicia **32**, **34**, **36** in the illustrated example, but not necessarily, are in the form of lines of stitching beginning on the label, and continuing across the pad **26** as shown at **38**, **40**, **42**. These lines of stitching would be in a conspicuously colored material, as compared to the color of the pad and the cuff body, so as to be conspicuously displayed to the user of the cuff.

The construction of the pad is of interest. It is intended to cooperate with a mating pad **44**, stitched to the body **19**, on the outer surface of the body, at the end of the body opposite from the pad **26**. Pad **44** and pad **26** are disposed in face to face contact when the cuff is applied to the arm A, during normal usage of the device, and in these circumstances, the pads adhere to one another to maintain closure of the cuff. The pads are separable fastening devices comprising face to face members each provided with a very large number of closely spaced, interengagable hooking elements. Thus, the elements on pad **26** may be hooks made of flexible, resilient material, while those of pad **44** would be loops also of a flexible, resilient material. These pads are al-

ready known, being fully disclosed in U.S. Pat. No. 3,009,235 and sold under the trademark Velcro (a trademark of Velcro Corporation, 681 5th Ave., New York, N. Y.).

For the purposes of the present application, it is sufficient to note that the pads **26**, **44** together constitute cooperating connecting means of the opposite end portions of the cuff, which connecting means normally maintains cuff closure if the cuff is used within the limits of assured accuracy, or within a toleranced excess value above said limits. It is further sufficient to note that when the cuff is used above the predetermined, maximum safe limit, the connections will separate when gas pressure is applied to the occluding bladder, preventing use of the cuff beyond the prescribed limits.

In normal use of the cuff, it is wrapped about the arm in the manner shown (FIG. 3), and in the circumstances, pads **26**, **44** will be brought into face to face contact, and pad **26** will be pressed against the pad **44** to adhere thereto and maintain closure of the cuff. It is important to note that indicium **30** bears the value N, while the indicia **34**, **36** bear the values 10, 20 percent respectively.

The preferred ratio of bladder width to arm diameter is 1.2 to 1, that is, the width of the bladder (for example, 5 inches) is equal to the approximate diameter of the arm about which the cuff is wrapped. However, there may be accepted tolerance levels, for example 1 to 1.

It should be noted that the average sphygmomanometer scale is **300** mm. which is considerably higher than most abnormally high blood pressure recordings.

The procedure in taking blood pressure requires elevating the cuff pressure rapidly to considerably (30–40 mm. Hg.) above the systolic pressure as determined by the palpatory method. The cuff is then slowly decompressed at a rate of 2 to 3 mm. per heartbeat. Thus, at a blood pressure recording (by palpatation) of 250 cm. systolic the pressure should be raised to almost 300 mm. When this occurs on the disclosed cuff at a ratio greater than 1 to 1 (limb diameter to bladder width) the cuff fails to hold, thus insuring the recorder and those who rely on the written recording, with or without knowledge of patient limb size, that the cuff used has reasonably conformed to standard medical recommendations (i.e. gross error due to cuff sizing cannot occur). The magnitude of this error with current cuffs, which exceed standard recommendations by up to 50 percent, may result in errors as high as 60 mm.

In other words, during normal use of a blood pressure cuff, the user must apply the gas pressure rapidly to a value well above the highest blood pressure that would be expected. In accordance with the invention, a relationship is established between the holding power of the connecting means, and the value of this maximum, normally applied pressure required for taking a recording.

If the cuff is used within the prescribed ratio, that is, if the limb diameter is equal to or less than the cuff width, the indicium **32**, signifying "normal" use registers with the edge **46** of pad **44**, which edge is itself an indicium or reference point the location of which is to be observed in respect to the indicia **32**, **34**, or **36**. If indicia **32**, **46** register, the ratio of the limb diameter to the width of the cuff is 1 to 1. If indicium **46**, when the end portions of the cuff are overlapped, is to the left of indicium **32**, viewing the same as in FIG. 3, the limb diameter is less than the cuff width and an accurate reading is still assured.

If, however, the limb diameter exceeds the cuff width, it may be that the indicium **34** will now register with indicium or marking **46**. In these circumstances, the user has exceeded the recommended limit of assured accuracy, but not to a dangerous extent. The connecting means will thus continue to hold.

The connecting means will also hold if the user exceeds the limit of assured accuracy by 20 percent, that is in circumstances in which the marking **36** registers with the reference line or marking **46**.

Beyond the 20 percent high tolerance, however, the cuff is designed to open upon inflation to the extent described above when one carries out the accepted, normal technique of taking a blood pressure recording. This is by reason the fact that, in these circumstances, the entire width of pad **44** is not in mating, adhering relationship to the pad **26**. The reduction in the area of connection between the two pads causes the loss of holding power, and under the cuff-opening force resulting from the normal inflation of the bladder, the loss of holding power is such as to cause the cuff to open, thus incorporating the "fail-safe" characteristic previously described herein.

Thus, the possibility of gross inaccuracies due to improper sizing, which possibility has been noted in other cuffs, is minimized in carrying out the present invention. Intentional or inadvertent disregard of the safe limits of assured accuracy as set forth in the illustrated example, is obviated.

It is also to be noted that the selection of the location of the indicia, in relation to the dimensions of the bladder width and the location and form of the connecting means, is such as to cause the cuff to embody standards acceptable both to the American Heart Association and the World Health Organization schools of thought, and has a practical effect of resolving differences between these schools as academic. In other words, the indicia are selected and located, in reference to the connecting means, such as to satisfy all recognized, known scientific authority heretofore speaking on the establishment of standards as to cuff width in relation to limb diameter. One need only apply the cuff as described above, after selecting the proper main size, to assure the taking of an accurate reading, without regard to the particular school of thought favored by the user.

A further discussion of the capability of the invention to resolve differences between the American Heart Association and World Health Organization schools of thought is believed appropriate. If one takes the standard adult bladder which is 12 to 13 cm. × 23 to 26 cm., which is recommended by the American Heart Association and applies the principle of marking it with a 1 to 1.2 ratio, this gives 75 percent limb encirclement at this particular size. World Health Organization suggests that a 14 cm. width × 42 cm. length cuff obviates the need for concern on the width of a blood pressure cuff, since the cuff (bladder) completely encircles the arm. In other words, one school of thought holds that

width is the key factor if the 1 to 1.2 ratio is held, while the other school of thought holds that the length is the key factor, provided the width is 14 cm. In essence, my cuff resolves this difference by marking at the 1 to 1.2 ratio which in turn gives 75 percent encirclement (on adult, 100 percent on other sizes). Other sizes are then provided which conform to complete encirclement.

I claim:

1. A blood pressure cuff comprising:

a flexible, elongated body having end portions overlapping in an operative, limb encircling disposition, said body having an occluding bladder, connectable to a source of fluid under pressure;

holding means for releasably connecting the overlapping end portions of said elongated body;

said holding means having a predetermined holding force, related to the ratio of limb diameter to the width of said bladder; and

said holding means being operable to release said overlapping end portions in response to the application of a separating force, during the operative application of said cuff, which separating force is in excess of said predetermined holding force.

2. A blood pressure cuff according to claim 1, wherein said holding means comprises mating connecting elements on said end portions; and

said connecting elements have a holding force which decreases to the extent of reduction of the area of overlap of the end portions.

3. A blood pressure cuff as in claim 2, wherein said connecting elements comprise an area of hook members on one end portion in face-to-face contact with and separably interengaging an area of loop members on the other end portion.

4. A blood pressure cuff as in claim 3 in which said areas are increasingly offset from one another and hence have progressively less contact with each other, in proportion to a progressively greater reduction in the extent of overlap of said end portions.

5. A blood pressure cuff comprising:

a. a flexible, elongated body having end portions overlapping in an operative, limb encircling position of the body, said body having an occluding bladder connectable to a source of fluid under pressure;

b. means on the body utilizing the ratio of limb diameter to the width of the occluding bladder, to indicate a limit of assured accuracy in the recording of one's blood pressure; and

c. separable connecting means on the respective end portions releasably holding the same together in the limb-encircling position of said body.

6. A blood pressure cuff as in claim 5 wherein said first-named means comprises indicia on at least one of said end portions indicating the extent of overlap of the end portions in terms of the extent of deviation, if any, from a predetermined norm.

7. A blood pressure cuff as in claim 6 wherein said indicia are spaced longitudinally of said one end portion.

8. A blood pressure cuff as in claim 7 wherein an indicium is provided on the other end portion, whereby the extent, if any, of deviation from said norm is determined by visual observation of the angular position of said indicium in respect to any of the indicia of said one end portion in the limb-encircling position of the body.

9. A blood pressure cuff as in claim 8, said second-named means being operative to lose holding power with resultant opening of the cuff in response to the normal application of pressure fluid to the bladder under conditions in which the ratio of limb diameter to the bladder width is in excess of a predetermined value, and in which said ratio is visibly shown to be in excess of said value by reference to the relative displacement of the indicia of the respective end portions.

10. A blood pressure cuff as in claim 9 wherein said second-named means comprises strips of hook members and loops on the respective end portions, separably interengaging to hold the end portions together, said indicia extending across at least one of said strips as a visual reference of the extent to which said strips may be angularly displaced without a critical loss of the holding power thereof.

* * * * *