[54] MEANS FOR COLLECTING SPECIMENS OF URINE

[76] Inventors: Donald M. Gleason, 5402 E. Grant Rd. Suite B-4, Tucson, Ariz. 85716; Manfred R. Bottaccini, Rt. 6 Box 326 V, Tucson, Ariz. 85704; Robert J. Reilly, 5402 E. Grant Rd. Suite B-4, Tucson, Ariz. 85716

[22] Filed: Jan. 22, 1971


Related U.S. Application Data


[51] Int. Cl. ....................... A61b 10/00
[58] Field of Search .......... 128/2 F, 2 R, 295, 128/294; 4/110; 73/425.4

[56] References Cited

UNITED STATES PATENTS

3,161,891 12/1964 Bauman ..................... 4/110
3,601,125 8/1971 Moss ..................... 128/295
994,884 6/1911 Stewart ..................... 128/295
3,114,916 12/1963 Hadley ..................... 4/110

231,487 8/1880 Smith et al.................. 128/295
2,968,046 1/1961 Duke ..................... 4/110
3,194,238 7/1965 Breece, Jr.................. 128/295

FOREIGN PATENTS OR APPLICATIONS

1,144,483 3/1969 Great Britain.................. 128/295

Primary Examiner—Kyle L. Howell
Attorney—Roylance, Abrams, Berdo & Kaul and J. Hanson Boyden

[57] ABSTRACT

A device for collecting, from human females, specimens of urine substantially free from external contamination. The device includes a hollow body having a mouth adapted to be placed around the meatus of the female and between the labia, a conduit passing through one wall of the hollow body and having an opening at one end thereof within the hollow body and completely spaced from the walls of the hollow body for receiving the high trajectory uncontaminated portion of the urine flow, a collecting vessel at the other end of the conduit for collecting the uncontaminated urine, and means for separately conducting the urine flow not entering the opening.

5 Claims, 13 Drawing Figures
MEANS FOR COLLECTING SPECIMENS OF URINE

This is a continuation-in-part of U. S. Pat. application Ser. No. 31,204 filed Apr. 23, 1970, now abandoned. This invention relates to a device for collecting specimens of urine from female patients, and more particularly for collecting specimens of urine substantially free from external contamination, and truly representing the conditions of the main body of the urine as it actually exists in the bladder.

The initial stream, at the beginning of the voiding operation, contains all of the accumulated debris and mucous collected in the urethra since the previous voiding, and therefore, either by itself or mixed with the rest of the urine, does not constitute a true sample of the condition of the main body of the urine in the bladder free from this initial flow. The initial discharge must therefore be separated from the rest of the urine in the bladder before taking a sample of this main body of urine. The initial discharge is washed out by the first few spoonfuls of normal urine as the flow continues.

The principal object of the invention is to devise means for effectively separating this initial discharge from what we shall call the "midflow stream." We have discovered that the initial stream is discharged from the urethra with relatively low energy or velocity, while the midflow stream comes out with relatively high energy or velocity. The trajectories of the two streams are therefore widely different. Based on this discovery, we have devised as one form of the invention, apparatus which enables us to automatically separate and direct into different conduits the liquid delivered by the two streams.

This apparatus comprises a rigid body formed with a relatively wide mouth, shaped to be inserted between the labia so as to separate them. The rim of this mouth encloses but is spaced from the meatus from which the streams issue. This body is provided with two rigidly connected conduits, these conduits, when the device is in use, having vertically extending portions, the lower open end of at least one of which is connected with the upper end of a vertically disposed receptacle. The difference in the trajectories of the two streams causes the streams to selectively enter the two conduits and thus be effectively separated.

In another form of the invention, a valve is used to block flow through one conduit while the initial stream is discharged from the other, thus effectively separating the two streams.

In order that the invention may be readily understood, reference is had to the accompanying drawings, forming part of this specification and in which:

FIG. 1 is a diagrammatic fragmentary side elevation showing in broken lines the patient in sitting position, and illustrating how she herself can apply our device without any help from an attendant;

FIG. 2 is a vertical section, on an enlarged scale, throughout the device when in position for use, parts of the patient's anatomy being indicated in broken lines;

FIG. 3 is a front elevation of the body of the device when viewed from the plane of the line 3-3 of FIG. 2, looking in the direction of the arrows;

FIG. 4 is a fragmentary section on the line 4-4 of FIG. 2, looking in the direction of the arrows, parts of the patient's anatomy being illustrated in broken lines;

FIG. 5 is a side elevation of a modified form of the invention, parts being shown in section, and portions of the patient's anatomy being indicated in broken lines, as in FIG. 2;

FIG. 6 is a front elevation of the modification shown in FIG. 5, looking from the line 6-6 of FIG. 5 in the direction of the arrows;

FIG. 7 is a vertical section through the body and conduits only of the form of the invention shown in FIG. 2, all other parts being omitted for the sake of clearness;

FIG. 8 is a vertical section through the body of a further embodiment of the invention;

FIG. 9 is a front elevation of the device of FIG. 8;

FIGS. 10 and 11 are respectively a front elevation and a vertical section through a further embodiment of the invention, and FIGS. 12 and 13, are, respectively, a front elevation and a vertical section through yet another embodiment in accordance with the invention.

Referring to the drawings in detail, and more particularly first to FIGS. 1, 2, 3 and 4, our device comprises a rigid body 1, formed of suitable plastic, and having a relatively large, laterally presenting mouth 2. The device is designed to be applied to the patient in natural sitting position, and when so applied, the body and mouth are disposed in substantially vertical position, the mouth being of vertically elongated shape, as clearly shown in FIG. 3. A barrier 3, closing the lower end of the mouth, is preferably employed to aid in controlling the flow of urine.

Associated with body 1 are two downwardly directed conduits 4 and 5, the conduit 4 opening directly from the bottom of the body, and the conduit 5 extending horizontally from the upper part of the body and then bending downwardly. The conduit 5 may either be formed integral with the body, or separately fabricated and attached to the body, as by welding, as shown in FIGS. 2 and 7.

The purpose of these two conduits, connected with opposite ends of the body is to effectively separate the initial discharge from the urethra from the midstream urine discharge coming from the bladder later on, after the elapse of a certain time interval, as hereinafter described.

As shown in FIG. 2, the end of the conduit 4 is illustrated as being formed with a vent 8 and as having a receptacle 6 secured thereto, but this conduit may, in most cases, be connected to waste. The end of conduit 5, however, has a receptacle 7 secured thereto, provided with a vent 9. This receptacle is necessary to collect the desired specimen of urine.

In order to illustrate the operation of the device we have endeavored to indicate in FIGS. 2 and 4 some of the parts of the female anatomy. Thus, the urethra leading from the bladder is shown at A, and the orifice at the outer end, from which the streams issue, and which is called the meatus, is shown at B. The position of the labia, when the device is in place, is indicated at C.

It will be noted, by reference to FIGS. 2 and 3 that the upper end of the mouth 2 is rather narrow or pointed, as shown at 2a.

OPERATION

Normally, the meeting sides or edges of the labia, especially the labia majora, at each side of the center, are substantially in contact, overlying and covering up the meatus. For the purpose of obtaining clean and uncontaminated samples of urine as it existed in the bladder, it is desirable to get the labia out of the way, so that the
stream of urine may issue freely from the meatus without coming in contact with the labia. To achieve this, the pointed end 2 a of the mouth 2 is inserted between the lower part of the labia and the mouth is then pushed upwardly and inwardly until it completely separates the labia and uncovers the meatus, as shown in FIGS. 2 and 4. When in this position, the rim of the mouth surrounds and encloses the meatus, but is spaced from it on all sides, especially at points above and below it. When inserting the device between the labia, the pushing may be continued until further movement is stopped by engagement of the rim of the mouth with the vestibule, but as illustrated in FIG. 4, it is not necessary for the rim of the mouth to contact the vestibule.

With the device in position as shown, voiding is begun. As above mentioned, the initial discharge from the urethra is likely to be mixed with all of the accumulated debris and mucus collected in the urethra, and is not suitable for diagnostic purposes as a true specimen of the urine existing in the bladder. Also, as already mentioned, this initial discharge issues with relatively little energy and at relatively low velocity. This initial stream therefore follows a trajectory somewhat as indicated by the dotted line X in FIG. 2, passing through the conduit 4 at the bottom of the body into the receptacle 6 or waste.

After a brief interval, and without interruption of the voiding, however, the midflow stream automatically begins; as previously mentioned, this midflow stream issues from the meatus at relatively high velocity, and thus follows a trajectory somewhat as shown by the broken line Y. This is discharged substantially horizontally, passing into the conduit 5 through the opening 5 a. It strikes the inner curved surface of the wall of this conduit and is thereby deflected downwardly, as indicated at Z, into the receptacle 7. The specimen collected in this receptacle is a true, uncontaminated sample of the urine contained in the bladder, and may be used with confidence for diagnostic purposes.

The opening 5 a, providing communication between the body 1 and conduit 5 is preferably somewhat restricted; that is to say, it is made as small as practicable so that if the stream of midflow urine should tend to spray before reaching the opening, only the central portion of the stream will enter said opening, while the outer fringes of the spray will impinge upon the surrounding surfaces and trickle down the same to waste. This tends to further reduce the possibility of contamination of the specimen collected in the receptacle 7.

It will be particularly noted that while the rim 2 of the mouth completely surrounds and encloses the meatus, it is spaced laterally therefrom in all directions, so that the interior of the mouth and body provide sufficient free space to permit the streams to follow different trajectories.

While it has been assumed in the preceding discussion that in most cases the only desired specimen is that obtained during the midflow stream and collected in receptacle 7, while the initial discharge may be discarded, it will be recognized that, for purposes of certain diagnostic procedures, it may be desirable to collect and retain the initial flow in as undiluted form as possible. A significant advantage of the invention is that the separation is accomplished automatically without special preparation, instruction or apparatus other than that shown in FIGS. 1-4, and that the specimens collected in either or both of the receptacles 6 and 7 can be examined, if desired.

A modified embodiment of the invention, illustrated in FIGS. 5 and 6 shows another way of effectively separating the initial discharge from the desired midflow stream.

While the embodiment shown in FIG. 2 operates automatically to effect the separation, the modified arrangement of FIGS. 5 and 6 is not automatic but requires manual adjustment by the patient.

Referring now in detail to FIGS. 5 and 6, this form of the invention includes a rigid body 1 having a laterally presenting mouth 2, and conduits 4 and 5, generally similar to the arrangement of FIG. 2. In the modified form, however, a valve 10 is provided, extending across the entrance to the conduit 5, and when closed, as shown in full lines in FIG. 5, blocking the flow of liquid into this conduit. The valve 10 is secured at its end to a transverse shaft 11, journaled in the conduit, and having a manually operable handle 12, by means of which it may be oscillated so as to swing the valve from the full line closed position, to the open position shown in broken lines, or visa-versa.

When it is desired to take a urine specimen, the mouth of the device is inserted between the labia, as described in connection with FIG. 2, and the valve 10 shifted to closed position, as shown in full lines. Then when voiding begins, the initial discharge stream, follows a path somewhat as indicated by the dotted line X', impinging against the closed valve 10, and is deflected downwardly, and escapes through conduit 4 to waste.

After a short interval, the valve 10 is manually swung to the open, dotted line position, leaving the entrance to conduit 5' free and unobstructed. By this time, the midflow stream has started, and, moving at relatively high velocity, follows a straight path from the meatus B into the entrance of conduit 5', somewhat as indicated by the broken line Y'. It then strikes the curved wall of the conduit and is deflected downwardly into the receptacle 7, as in FIG. 2.

It will of course be understood that the specific arrangement of the valve as shown in FIGS. 5 and 6 is illustrative only, as many other manually adjustable arrangements for preventing the entrance of the initial discharge into the receptacle 7 can be readily devised.

A further embodiment shown in FIGS. 8 and 9 in accordance with the invention includes a substantially rigid body indicated generally at 20 having a downwardly extending portion 21 and a laterally extending portion 22 which are joined to form an essentially elbow-shaped hollow body or conduit. Downwardly extending portion 21 is coupled to a container 23, only the upper portion of which is shown in FIG. 8, container 23 constituting specimen storing means.

Body portion 22 terminates in a laterally presenting mouth 24 which is essentially oval in shape and which is formed, as previously described, to fit between and separate the labia and to surround, but remain spaced from, the meatus during the voiding of urine to collect a sample. At the lower end of mouth 24 the material of the body is cut away to form a notch 25 to permit disposal of urine which is not desired to be collected in the specimen.

A barrier 26, which can be formed integrally with the remainder of the body, extends transversely across the hollow interior or the body and is spaced inwardly from
mouth 24. The barrier is joined at the lower end side interior walls of the body but terminates in an upper edge 27 which is substantially closer to the upper interior wall of the body than to the lower interior wall thereof, thereby defining a passage of relatively small size, compared with the total size of the mouth, near the top of the portion 22.

As previously described, the mid-stream portion of the urine voiding is characterized by a significantly higher pressure than either of the initial voiding stream or the final voiding stream. The object of the embodiment shown in FIGS. 8 and 9 is to provide a passage through which only this highest velocity portion of the voiding stream can pass to the specimen storing means, this passage being defined by the upper interior walls of body portion 22 and the upper edge 27 of barrier 26. The highest portion stream, identified as Y in FIG. 8, passes over the barrier into a passage on the back wall of the body and, falls, as indicated at Z, into the receptacle 23. Lower pressure portions of the stream indicated at X, contact barrier 26, flow downwardly therefrom, and are discharged through notch 25. It will therefore be seen that the upper edge 27 and the upper interior walls of the body form a passage which is approximately indicated by the dotted line 28 in FIG. 9 through which only the desired portions of the specimen can pass.

A further embodiment in accordance with the invention is shown in FIGS. 10 and 11 in which a first body portion 30 terminates in a laterally presenting mouth 31 having a suitable curvature, and being suitably dimensioned to fit between the labia and to surround the meatus. It will be observed that the mouth terminates in an edge which is continuous around the sides and the upper portion of the mouth but is interrupted at the lower portion thereof to create a notch or recess 32. Inwardly spaced from the mouth and closing the back of the cavity formed by body 30 is a back wall 33, the lower edge of which terminates at notch 32. A generally rectangular projection 34 protrudes generally perpendicularly from wall 33 toward mouth 31, extend- ing into the cavity. The rectangular projection constitutes four relatively thin walls defining a rectangular opening 35 which extends through wall 33 and into a second portion formed by an adjacent wall 36. Body portion 30 is essentially an L-shaped or elbow structure having a conduit extending therethrough, the conduit being an extension of opening 35. Liquid entering opening 35 passes through the conduit 37 and is directed downwardly. The lower end of body 36 terminates in a nip- ple portion 38 of diminished outer diameter, the diameter thereof being dimensioned to fit within the neck 39 of a container 40.

Body 37 also carries two laterally extending tab members 41 and 42 which protrude outwardly from the outer surfaces of body 37 and are advantageously formed integrally therewith. In use, as described with reference to FIG. 1, the user places her first and second fingers beneath tabs 41 and 42 with the ends of the fingers pointing in the direction of the mouth of the device. The upper edge of mouth 30 is then inserted at the lower end of the labia, separa-
rating the labia, and the device is moved upwardly until the mouth is essentially in the same position as that shown in FIG. 2. During voiding, the initial, or low-pressure, portion of the stream impinges against the lower portion of wall 33 and is discharged through notch 32. The midstream, or high-pressure portion of the stream is characterized by a higher velocity and a flatter trajectory which enters opening 35 in projection 34 and passes downwardly through conduit 37 into container 40. The protruding walls 34 prevent any liquid impinging forcefully on the lower portion of wall 33 from inadvertently entering opening 35, thereby assuring a specimen which is uncontaminated by earlier portions of the stream and is sampled only from the mid-stream portion.

Yet another embodiment is shown in FIGS. 12 and 13, this embodiment being of a type which is designed to separately collect both the early portions of the stream as well as the midstream portions. As shown in FIGS. 12 and 13, a body portion 50 opens at a laterally presenting mouth 51 which is continuous around the opening of the cavity formed by body 50. A conduit 52 extends upwardly through the lower portion of body 50, conduit 52 being of substantially cylindrical shape and of somewhat smaller diameter than the width of the interior of body 50. The upper end of conduit 52 is closed by an upper end wall 53 and has a front opening 54 which faces in the same direction as mouth 51. The lower extremity of opening 54 is spaced above the lower wall of the cavity formed by body portion 50.

Conduit 52 also extends downwardly from the outer surface of body 50 and terminates in a nipple portion 55 of reduced diameter which is dimensioned to fit within the neck 56 of a container 57. As seen in FIG. 13, a central passageway 58 within conduit 54 is available to conduct fluid between opening 54 and the opening at the lower end of nipple 55.

At the rear of body portion 50 a semi-annular wall portion 59 interconnects body portion 50 with a sub-
stantially cylindrical body portion 60 which is, essen-
tially, a continuation of body portion 50. Body portion 60 defines a second cavity which communicates with the cavity adjoining the mouth 51 so that fluid which does not enter opening 54 can pass around conduit 52, through the cavity within body portion 60 and into a conduit 61 which lies at the rear of body 60 and ex-
tends in a downward direction. It will be observed that the floor of the cavity formed by body portion 60 is a continuation of the floor of the cavity formed by body portion 50, and that the floor together form a continu-
ous downwardly sloping surface, in use, leading to con-
duit 61. The lower rear portion of body 60 terminates in a nipple of reduced diameter which is dimensioned to fit within the neck 62 of a container 63.

Body portion 60 is also provided with laterally ex-
tending tabs 64 and 65 which extend outwardly from the outer surfaces of the body and can be integrally formed therewith.

The use of the apparatus of FIGS. 12 and 13 is similar to that of FIGS. 10 and 11 wherein the user places her first and second fingers beneath tabs 65 and 65 and inserts the device as previously described. It will be ob-
served that urine entering mouth 51 will necessarily be caused to pass either through opening 54, through con-
duit 58 and into container 57, or around conduit 52, through body 60 and into container 63. As previously described, only the midstream portions will have suffi-
cient pressure to enter opening 54, confining the mate-
rial in container 57 to sample from that midstream por-
tion.

While certain advantageous embodiments have been chosen to illustrate the invention, it will be understood by those skilled in the art that various changes and
modifications can be made therein without departing from the scope of the invention as defined in the appended claims.

What is claimed is:

1. A device for collecting a sample of urine from the midstream portion of a voiding stream of a human female comprising:
   a hollow body having an oval laterally presenting mouth, an upper surface and side walls, and a back wall opposite said mouth, said mouth adapted to fit between and separate the labia and at least partially surround the meatus and remain spaced therefrom during voiding;
   a conduit having an upper end and a lower end, the upper end of said conduit extending into said hollow body through a wall and having an opening at the end completely spaced from all of the walls of said hollow body and facing said mouth so that no urine flowing along the surface of any of the walls may flow into the opening and through which urine samples from the midstream portion can pass, and the lower end of said conduit having means for connecting the conduit to a specimen container; and
   a specimen collecting container, mounted to said means for connecting, to collect the urine entering said opening.

2. A device for collecting a sample of urine from the midstream portion of a voiding stream of a human female comprising
   a hollow body having an oval laterally presenting mouth, upper and side walls, and a back wall opposite said mouth, said mouth adapted to fit between and separate the labia and at least partially surround the meatus and remain spaced therefrom during voiding;
   a generally elbow-shaped conduit having an upper end and a lower end, the upper end of said conduit extending into said hollow body through said back wall and having an opening at the end completely spaced from all of the walls of said hollow body so that no urine flowing along the surface of any of the walls may flow into the opening and through which urine samples from the midstream portion can pass, and the lower end of said conduit having means for connecting the conduit to a specimen container; and
   a specimen collecting container, mounted to said means for connecting, to collect the urine entering said opening.

3. A device according to claim 2 wherein said mouth includes means defining a notch at the lower end thereof for permitting immediate discharge of all of the urine not flowing into said opening and preventing the accumulation of any urine in said hollow body.

4. A device according to claim 3 wherein said upper end of said conduit is a hollow projection which is substantially rectangular in cross-section and which protrudes into said hollow body substantially perpendicularly from said back wall.

5. A device according to claim 4 wherein the upper end of said conduit protrudes into said hollow body from said back wall a distance substantially equal to one-third the length of the upper wall of said hollow body.

• • • • •