May 11, 1948. C. DAVIES 2,441,237

TUBAL INSUFFLATOR

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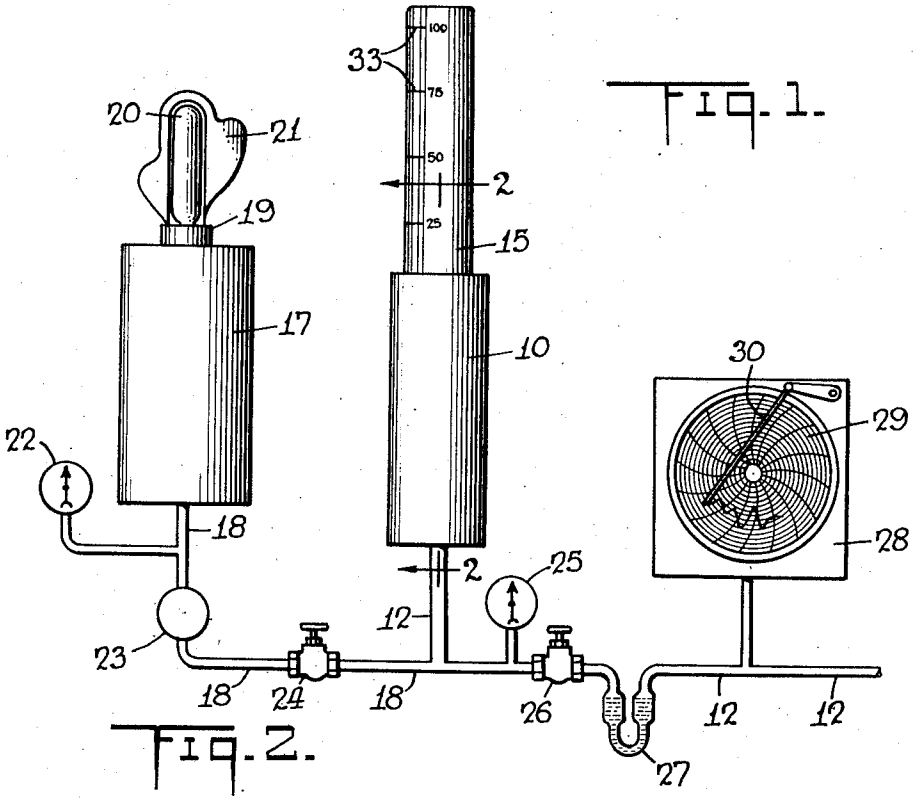
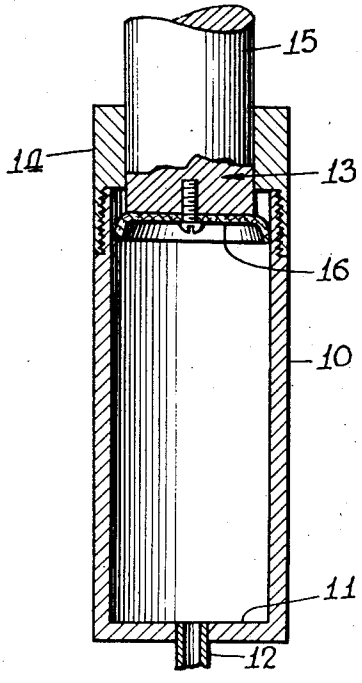


Fig. 1.

Fig. 2.



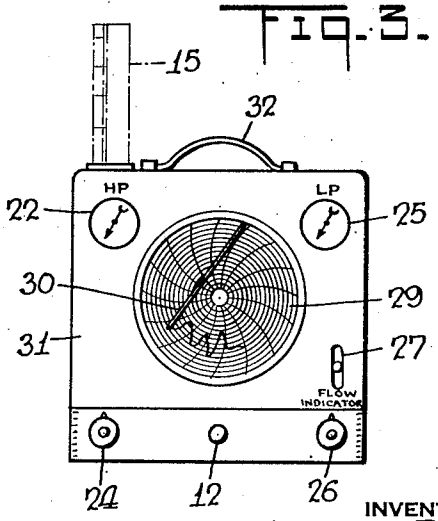


Fig. 3.

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Fig. 4.

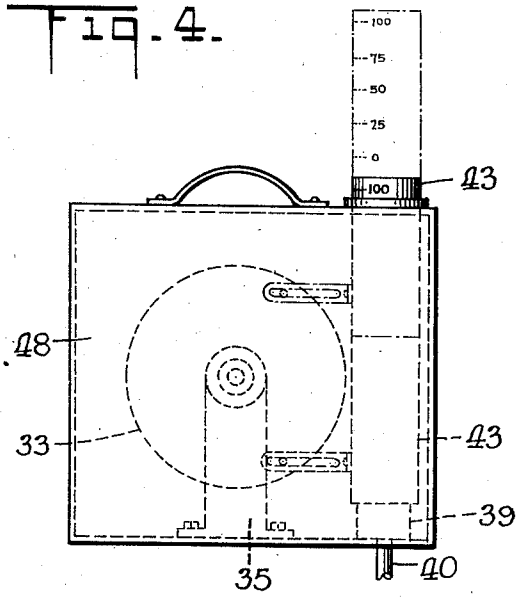


Fig. 5.

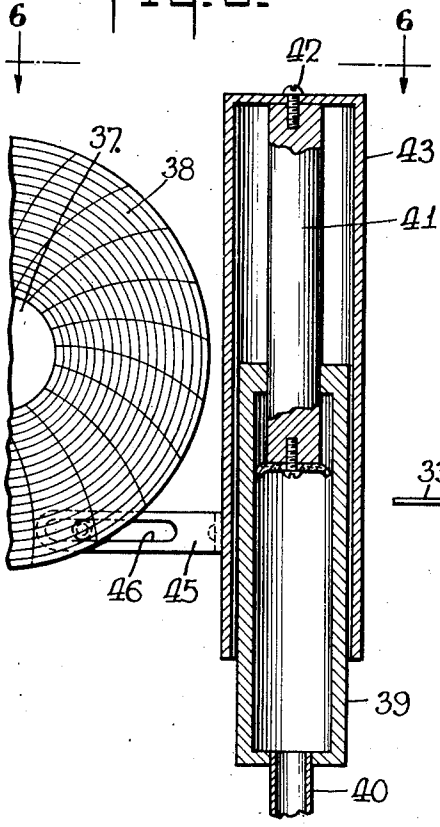
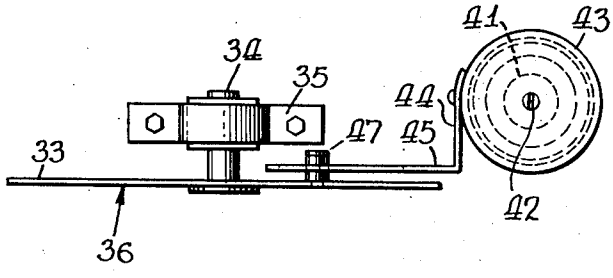


Fig. 6.



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Patented May 11, 1948

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2,441,237

TUBAL INSUFFLATOR

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Application December 28, 1946, Serial No. 718,985

4 Claims. (Cl. 128—2)

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My present invention relates generally to surgical apparatus, and has particular reference to a tubal insufflator.

For diagnostic and other purposes, it is a well-known procedure to introduce carbon dioxide gas under pressure into the uterus, for the purpose of detecting and possibly opening a constriction in one or both of the Fallopian tubes.

One of the difficulties encountered in carrying out a procedure of this character arises from the fact that there are limits not only to the mass of gas which may be safely introduced into the body, but also to the pressure which may safely be used. For example, it is generally recognized that a pressure exceeding 200 mm. of mercury (about 4.2 lbs. per square inch) is dangerous and must be avoided; and that no more than 100 c. c. of gas at that pressure may be safely introduced. The doctor must constantly exercise great care that neither the maximum pressure nor the maximum mass of gas is exceeded. In view of the fact that the doctor must also control the introduction of the gas at a slow rate, and direct his attention to the pressure variations that occur as the insufflation proceeds (since it is these fluctuations in pressure which impart the clinical information desired), it is apparent that the procedure is one which requires unusual care and skill.

It is a general object of my present invention to provide an improved apparatus by means of which a tubal insufflation procedure may be carried out with enhanced ease and simplicity, and with all danger of excessive pressures, or of the introduction of excessive quantities of gas, automatically avoided.

Among the more particular objects of the invention are the provision of coordinating instrumentalities whereby the doctor may readily observe and thereby control the slow rate of introduction of the gas, whereby the quantity of gas and the exact pressure may be constantly indicated, and whereby a permanent record may be produced of the moment-to-moment variations in pressure which take place.

It is also an object of the invention to provide an improved apparatus of this character in the form of a convenient, compact, readily portable, and relatively inexpensive unit whose operation is relatively simple and requires a minimum of skill.

I achieve these general objects and advantages, and such other objects and advantages as may hereinafter appear or be pointed out, in the manner illustratively exemplified in the accompanying drawings, in which:

Figure 1 is a diagrammatic representation of the associated instrumentalities entering into an apparatus of the present character;

Figure 2 is an enlarged cross-sectional view taken substantially along the line 2—2 of Figure 1;

Figure 3 is a front elevational view of a complete unit of portable character;

Figure 4 is a diagrammatic view of a modified assembly of certain of the elements;

Figure 5 is a cross-sectional detail view of the essential elements of the modified construction of Figure 4; and

Figure 6 is a fragmentary view taken along the direction 6—6 of Figure 5.

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Referring first to Figures 1–3, the main element of the present apparatus consists of an upstanding cylinder 10 having a bottom wall 11 with which a conduit 12 communicates. Mounted in the cylinder is a plunger 13 of predetermined weight, freely movable in an up-and-down direction. The mechanical assembly of these parts may be of any suitable character, and I have illustratively shown the cylinder 10 provided with a bored top wall portion 14 in screw-threaded engagement with the body of the cylinder, the plunger 13 having a cylindrical rod-like stem 15 extending upwardly through this bore. At its inner end, the element 13 may be provided with a washer or disk 16 of leather or the like, establishing a gas-tight yet slidable contact with the interior surface of the cylinder 10.

The plunger is guided in its up-and-down movements by the engagement of the washer 16 with the walls of the cylinder, and by the engagement of the stem 15 with the portion 14. The latter portion is provided with an inwardly-directed shoulder whereby the rise of the plunger in the cylinder 10 is limited to a predetermined height.

As hereinbefore mentioned, the plunger is of predetermined weight, this weight being so chosen with respect to the cross-sectional internal area of the cylinder 10 that the pressure exerted upon the gas beneath the plunger is exactly some predetermined amount, preferably 200 mm. of mercury. Moreover, the cylinder 10 is of predetermined dimensions, so that when the plunger is in its highest position there will be a known mass of gas within the cylinder, preferably 100 c. c.

In accordance with my invention, a means is provided for feeding a limited supply of gas into the cylinder 10. One way of achieving this result is to provide a chamber 17 which communicates with the cylinder 10 through the pipe 18, and which is provided with a neck or similar attachment element 19 by means of which a gas cartridge 20 containing gas under pressure may be discharged into the chamber 17. Usually, this is accomplished by mounting the cartridge 20 in a holder 21 which may be screw-threaded into engagement with the fixture 19, these elements being provided with a means of known type which automatically pierces the cartridge 20 and allows the compressed gas in the cartridge to pass into

the chamber 17. Gas cartridges are well known per se, as are the elements 19 and 21 and the associated mechanism for achieving the desired result. Accordingly, the details of this structure have not been illustrated herein. The cartridge 20 may be of the conventional character which is available on the market and which contains carbon dioxide under a pressure of about 125 lbs. per square inch.

Interposed in the pipe 18 is a pressure gauge 22 by means of which the pressure in the chamber 17 may be constantly observed. Also interposed in the pipe 18 is a reducing valve 23 which causes the pressure of the gas emanating from it to be of some selected lesser value, e. g., about 6 lbs. per square inch. A manually controllable valve 24 is interposed between the reducing valve 23 and the cylinder 10.

The main portion of the conduit 12 extends to a cannula (not shown) adapted to be inserted into the body of the patient. Interposed in the conduit 12 is a pressure gauge 25, a manually controllable valve 26, a flow indicator 27, and a recording instrumentality 28. The pressure gauge 25 affords a ready reading of the pressure in the cylinder 10 and in the conduit 12 at any instant of time. The valve 26 permits the flow of gas through the conduit 12 to be accurately controlled. The flow indicator 27 (which may consist of a U-shaped transparent conduit portion containing water or other liquid through which the gas passes in the form of bubbles) affords a means for observing the approximate rate of flow of the gas, even though this rate be extremely low. The recording instrument 28 is of the well-known character which is adapted to receive a paper chart 29 which is slowly moved and upon which a stylus 30 is adapted to record pressure variations.

All of the foregoing apparatus may be conveniently associated in a single unit, as shown in Figure 3. A cabinet 31 is provided on its front face with a window through which the chart 29 and the stylus 30 are displayed, and through which the charts may be inserted and withdrawn at the commencement and conclusion of each insufflation procedure. The gauges 22 and 25 are also mounted in such a way that their dials are readable on the face of the cabinet 31. On the top wall, the cabinet may be provided with a handle 32, and this wall is also provided with an opening through which the plunger stem 15 extends.

At least a portion of the flow indicator 27 is exposed to view through the front wall of the cabinet, and at the bottom are the valves 24 and 26, as well as the exit portion of the conduit 12 to which the cannula may be secured in any desired fashion. The chamber 17 and the reducing valve 23 are also accommodated within the cabinet, and the fixture 19 is positioned in an accessible manner at any convenient portion of the cabinet wall in order that a recharging of the chamber 17 may be conveniently effected whenever necessary.

It will be observed from Figure 1 that the exposed surface of the plunger stem 15 is preferably provided with height indicia 33. The calibrations may be of any desired character, and I have illustratively shown markings which represent volume in cubic centimeters.

When the apparatus is used, there must first be an adequate supply of carbon dioxide gas in the chamber 17. This will be indicated by the reading of the gauge 22. If the supply needs replenishment, this is accomplished by means of a

cartridge 20 in the manner hereinbefore described.

With the valve 26 closed, the valve 24 is opened sufficiently to permit gas from the chamber 17 to enter the cylinder 10 and raise the plunger to its maximum height. The valve 24 is then closed to seal the communication between the chamber 17 and the cylinder 10. At this time, the pressure of the gas in the cylinder 10 may be slightly greater than the desired maximum of 200 mm., but by slightly opening the valve 26, the pressure may be readily brought down to the desired magnitude at which the upward pressure of the gas exactly equals the downward pressure of the plunger. The valve 26 is then closed.

At this stage, there will have been achieved the desirable result of isolating in the cylinder 10 a measured maximum mass of gas at a predetermined maximum pressure. More particularly, in the preferred design of the apparatus, there will be available for the doctor 100 c. c. of gas at 200 mm. pressure.

The doctor is then ready for the test, and as a first step he will insert a clean chart 29 into the recording apparatus 28, and will poise the stylus 30 in readiness for the desired recordation of pressure variations. A suitable cannula is then attached to the conduit 12, and inserted into the patient's body. Then, by manipulation of the valve 26, any desired quantity of the measured mass of gas may be slowly introduced, at an observable and controlled rate, into the patient. If the Fallopian tubes are open, the pressure recorded by the instrument 28 will initially rise as the uterus and tubes are filled with gas. The pressure will then fluctuate, slowly falling and rising, due to normal uterine contractions. If this normal condition is indicated, the doctor may discontinue the procedure, but even if he continues it, there is no possibility of introducing more than the allowable mass of gas, and at no time will the pressure of the introduced gas exceed the maximum safe amount. If there is an obstruction in one or the other of the Fallopian tubes, the pressure will initially rise, as before, and will either remain at the highest point (indicting an inability of the gas to effect passage), or will fall and then commence fluctuating (indicating that the obstruction has been eliminated). Obviously, pressure variations other than those alluded to may manifest themselves, but in each case these variations will have clinical significance and in no case will the maximum allowable pressure be exceeded, nor will the total amount of gas exceed the allowable safe maximum.

During the procedure, the downward movement of the plunger stem 15 will correspond to the flow of gas through the indicator 27, and will serve as a readily observable means to inform the doctor of the total amount of gas which has been introduced at any given stage of treatment.

In Figures 4–6 I have illustrated a modified construction in which the downward movements of the plunger stem are utilized for the purpose of actuating the chart support of the recording instrument.

As in the case of the known variety of recording gauge, indicated at 28 in Figure 1, the chart support 33 is in the form of a circular disk mounted for rotation about its axis. In the embodiment of Figures 4–6, this chart support is provided with a shaft 34 journaled in a bracket 35. On its front face 36, the chart support may be provided with the usual central elevation 37

which supports the paper chart **38**. This chart is shown in Figure 5, but has been omitted from Figure 6. For the sake of clearness, I have also omitted from each of Figures 4–6 the stylus or marking instrument which is well known per se.

The cylinder of predetermined volume is indicated by the reference numeral **39**. Communicating wth its bottom wall is the conduit **40** from which gas is expelled from the cylinder when the plunger **41** moves downwardly. This plunger is constructed substantially like that of Figures 1–3, but is secured at its upper end, as at **42**, to a sleeve or skirt **43** which encircles the cylinder **39**.

Carried by the skirt **43** is a bracket **44** which carries a slotted arm **45**. The slot **46** engages in slidable relation over a pin **47** carried by the chart support **33** on its rear face. Obviously, as the plunger **41** descends from its uppermost position to its lowest position, the slotted arm **45** will move from the upper to the lower of the positions indicated in Figure 4, and this will cause a rotation of the chart support **33** through an angle of approximately 90°.

The parts are so designed that the weight of the plunger **41**, together with the weight of its associated elements (the skirt **43**, the bracket **44**, and the arm **45**) is of predetermined magnitude, whereby the pressure of the plunger upon the gas in the cylinder **39** is always a predetermined maximum amount, preferably 200 mm. of mercury.

When the apparatus of Figures 4–6 is used, the cylinder **39** is first filled with gas, as hereinbefore mentioned, and a sufficient amount of gas is then bled through the outlet valve until the plunger **41** is in a freely floating condition, whereby the downward pressure is the maximum allowable amount. With the parts in this relationship, a chart **38** is applied to the support **33**, and the pen or other marking instrument is applied to the chart in readiness for the recording operation. The test then proceeds in the manner hereinbefore described, and as the plunger **41** descends, the chart support **33** is rotated, whereby the marking stylus is adapted to produce a pressure-variation chart of well-known character. Should the plunger discontinue its downward movement as the result of a tubal constriction, the chart will of course discontinue its corresponding rotative movement, but since this state of affairs necessarily calls for a discontinuance of the test, this interruption of chart movement is not material.

The advantage of the mechanism shown in Figures 4–6 as compared with the employment of a conventional recording gauge **28** (Figure 1) lies in its extreme simplicity, and in the substitution of a relatively inexpensive self-contained mechanism for rotating the chart, in lieu of the relatively expensive clock mechanism necessarily present in the usual commercially-available recording gauge.

The mechanism of Figures 4–6, together with the other elements of the apparatus as hereinbefore described, may be conveniently accommodated within a portable container **48**, diagrammatically indicated in Figure 4, and corresponding to the container **31** shown in Figure 3. For the sake of clearness of illustration, I have omitted from Figure 4 the dials and other elements which are mounted preferably in the front face of this container.

Upon the completion of any insufflation procedure, the doctor may readily remove the chart upon which the pressure variations have been recorded, and may, if he so desires, retain it in his files for further study or for record purposes.

It is to be understood that those skilled in the art may readily make minor changes in the details herein described and illustrated without necessarily departing from the spirit and scope of the invention as expressed in the appended claims.

Having thus described my invention and illustrated its use, what I claim as new and desire to secure by Letters Patent is:

1. In a tubal insufflator, an upright cylinder, a plunger of predetermined weight freely movable therein, means for conducting a limited supply of gas into said cylinder to raise the plunger, a conduit from said cylinder adapted to be connected with a cannula, and a valve in said conduit, whereby when said valve is opened the weight of the plunger acting on the gas in the cylinder will cause said gas to be discharged from the cylinder through said conduit, and whereby the pressure of said gas cannot exceed that which is created by the weight of the plunger and the quantity of said gas cannot exceed that which is contained in said cylinder.

2. In a tubal insufflator, the combination of elements set forth in claim 1, said means for conducting a limited supply of gas into said cylinder comprising a chamber adapted to accommodate a supply of gas under pressure, means for discharging a gas cartridge into said chamber, a pipe from said chamber to said cylinder, and a manually controllable valve in said pipe for sealing the communication between the chamber and cylinder, after the latter has been filled.

3. In a tubal insufflator, the combination with the elements set forth in claim 1 of a recording instrument interposed in said conduit and adapted to produce a permanent record of the moment-to-moment pressure variations in said conduit during the insufflation procedure, said instrument including a movable chart support, and means actuated by said plunger for moving said chart support.

4. In a tubal insufflator, the combination with the elements set forth in claim 1, of a recording instrument interposed in said conduit and adapted to produce a permanent record of the moment-to-moment pressure variations in said conduit during the insufflation procedure, said instrument including a movable chart support, and means actuated by said plunger for moving said chart support, said last-named means comprising a slotted arm carried by said plunger, and a pin carried by said chart support and projecting through said slot.

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