May 2, 1939. G. LYFORD 2,156,764

DIAGNOSTIC AND THERAPEUTIC APPARATUS

Filed June 11, 1937

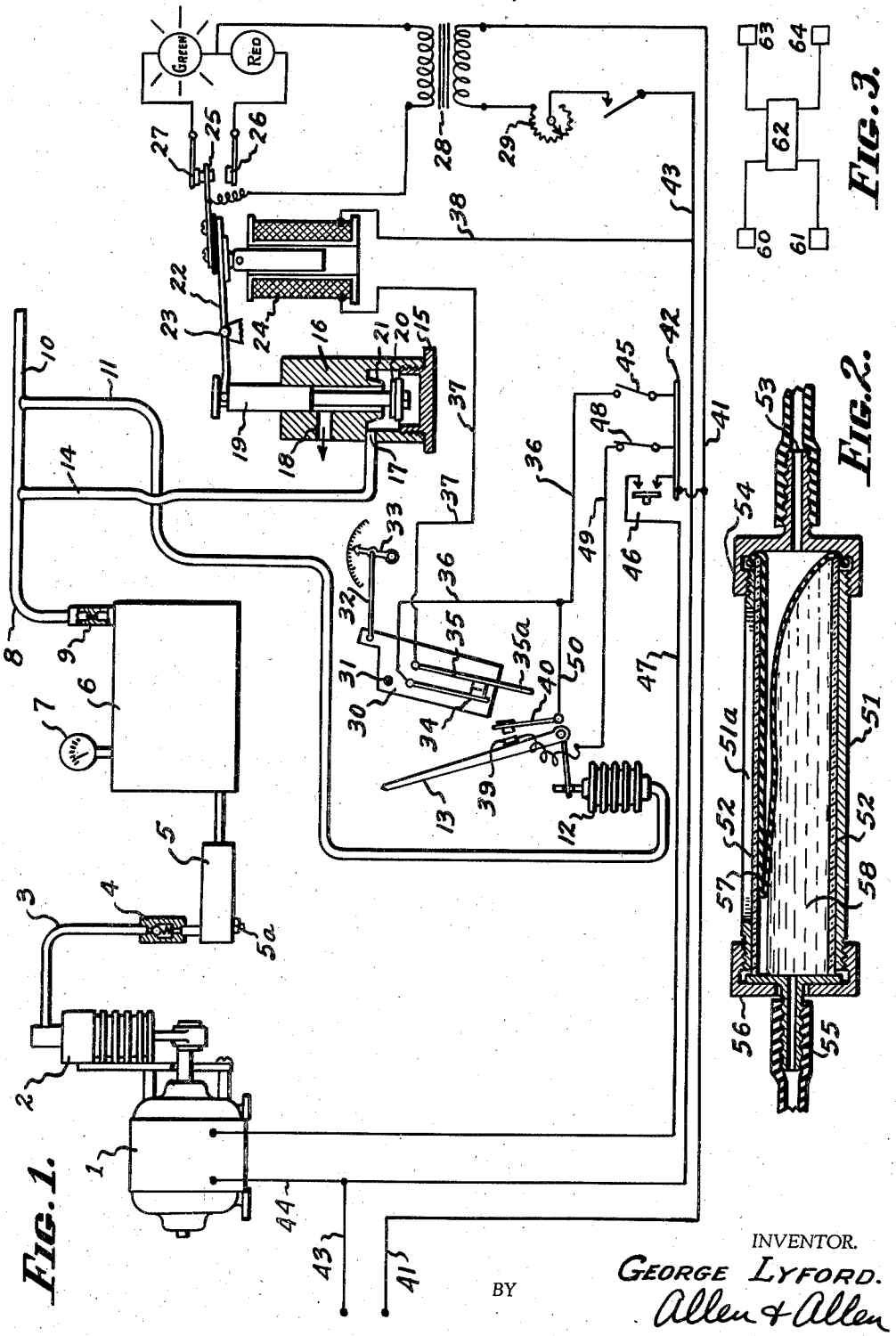

FIG. 1.

FIG. 3.

FIG. 2.

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Patented May 2, 1939 2,156,764

UNITED STATES PATENT OFFICE

2,156,764

DIAGNOSTIC AND THERAPEUTIC APPARATUS

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Application June 11, 1937, Serial No. 147,751

6 Claims. (Cl. 128—2)

My invention relates to diagnostic and therapeutic apparatus and more particularly to apparatus for procuring essential data in the differential diagnosis of pelvic pathology in the female.

During the past fifteen years during which trans-uterine insufflation has been increasingly used for the study of the Fallopian tubes, much work has been done and a great deal has been written concerning its diagnostic value, its dangers and its use as a therapeutic agent. Theoretically, at least, it would seem that this practice could also be used for studies of the normal physiology and this has to some extent been attempted.

Many difficulties have been encountered in connection with such studies and in connection with such treatments which have greatly impeded progress. One of these difficulties has been the inaccuracy of the apparatus. This has been perhaps the chief hindrance, although another difficulty of almost equal importance has been the discomfort to the patient resulting from the insufflation.

In view of the above mentioned difficulties it is an object of my invention to provide an apparatus for such studies and treatments as outlined above which will be extremely accurate and which will be simple and reliable in operation. Another object of my invention is to provide an apparatus which will be readily portable and which will be substantially automatic and foolproof in its operation.

These and other objects of my invention which will be described hereinafter or which will be apparent to one skilled in the art upon reading these specifications, I accomplish by that certain construction and arrangement of parts of which I shall now describe an exemplary embodiment. Reference is now made to the drawing which forms a part hereof and in which:

Figure 1 is a diagrammatic representation of the apparatus showing the electrical connections.

Fig. 2 is a detail cross sectional view of an oil cartridge, useful in connection with my apparatus.

Fig. 3 is a diagrammatic representation of an arrangement for indicating whether right or left or both tubes have opened.

Briefly in the practice of my invention, I provide means for building up pressure in a reservoir; I provide means for applying pressure to the patient and for indicating or recording the pressure which is applied to the patient; I provide means for causing the pressure to by-pass the patient; and in connection with these means I provide electrical means for by-passing the patient automatically when a predetermined maximum pressure is attained or when there is a drop in pressure, such as would be encountered as a result of the opening of a Fallopian tube.

Referring to Fig. 1 I have indicated an electric motor at 1 which drives a reciprocating pump 2. The pump 2 is connected by a line 3 provided with a ball-check valve 4 and a filter 5 to a reservoir 6. The reservoir 6 is preferably provided with an indicating device 7 for indicating the pressure within the reservoir. A line 8 leads from the pressure reservoir to other parts of the apparatus as will be described hereinafter and is provided with a pin-point orifice 9, whereby there is a slow leakage of gas through the line 8 under pressure from the reservoir 6. The line 10 communicating with the line 8 leads to the patient and in use is attached to a uterine canula. The line 11, which is in parallel with the line 10, leads to a conventional bellows pressure indicating device 12 which actuates a stylus 13. The stylus 13 is adapted to trace a recording line upon a chart driven by a synchronous motor in a conventional manner. It will thus be seen that the stylus 13 at all times indicates the pressure to which the patient is being subjected. Ahead of the junction between the line 8 and the lines 10 and 11, I provide a by-pass line 14 leading to a valve 15. Thus when the valve 15 is open manifestly no pressure will be applied to the patient and when the valve 15 is closed the pressure in the line 8 operates upon the patient through the line 10 and upon the stylus through the line 11. The valve 15 comprises a housing 16 in which there is an entrance port 17 and a discharge port 18. A plunger 19, upon which is mounted the closing member 20, fits in a bore in the housing 16 and the valve is closed when the member 20 abuts the seat portion 21. The valve plunger is actuated by a lever 22 pivoted at 23 and connected at one end to the plunger 19. A solenoid 24, when energized, operates to close the valve.

For indicating purposes I may provide an arrangement of red and green lights connected as shown. The end of the lever 22 carries a contact member 25 which is adapted to make contact with the contact member 26 when the valve is closed and with the member 27 when the valve is opened. I prefer to use six-volt red and green lights and, therefore, place in the line a step-down transformer 28. The intensity of illumination of light may be adjusted by the rheostat 29. From the above description it will be clear that

when the solenoid is energized to close the valve and cause pressure to be applied to the patient the red light will be illuminated and that when the valve is opened so that the patient is by-passed, the green light will be illuminated.

The maximum pressure device comprises a plate **30** pivoted at **31**, preferably on the panel and adapted to be turned by a knob on the control panel of the apparatus. The plate **30** is connected by means of a lever **32** to a pointer **33**, which cooperates with a calibrated scale so that the position of the plate **30** may be adjusted to any predetermined desirable maximum pressure. The plate **30** carries a fixed contact member **34** and a resiliently mounted contact member **35**, whereby the electrical contact between the members **34** and **35** is normally closed. It will thus be clear that assuming a circuit through the leads **36**, **37**, **38** and a source of electrical energy that the circuit will be broken when the member **35** is moved away from contact with the member **34**. It will also be clear that the point at which the contact between the members **34** and **35** will be broken depends upon the angular position of the plate **30** upon which the contact members are mounted.

The stylus **13** carries a contact member **39** which is adapted to make contact, shortly after the stylus has begun to move from its zero position, with a pivoted contact member **40**. The member **40** is arranged so that in its minimum position it is out of contact with the member **39** when the stylus is at zero. The member **40** is resiliently mounted in any conventional manner so that as soon as the stylus has begun to move and has made contact with the members **39** and **40**, this contact will be maintained as long as the pressure is increased or remains static. As soon as there is a decrease in pressure, the electrical contact between members **39** and **40** will be broken.

I will now proceed with a description of the electrical connections to the device. The power lead **41** is connected to one element **42** of a control. The other lead **43** is connected to the motor **1** and to the solenoid **24** by means of the leads **44** and **38** respectively. A lead **37**, as above described, connects the other side of the solenoid **24** with the member **35** and the member **34** is connected by means of the lead **36** to a switch element **45**. The switch element **46** is connected by means of a lead **47** to the motor **1** and the switch element **48** is connected by means of a lead **49** to the contact bar **39** on the stylus **13**. A lead **50** connects the contact member **40** with the lead **36**. It is to be noted that in accordance with this diagram, the switch member **48** is normally closed, while the switch members **45** and **46** are normally open.

The procedure in using this apparatus will now be described. The uterine canula at the end of the lead **10** is placed in or through the cervix with the usual technique for insufflations using surgical care for antisepsis. The patient is then placed in a slightly Trendelenburg position and the vagina filled with a mild antiseptic solution making a water seal. The canula is connected with the apparatus by means of the conventional Luer fittings. If a switch is provided in the lines **41** or **43**, such switch is first closed in order to supply current to the apparatus and the rheostat **29** is adjusted to provide the desired intensity of illumination of the indicating lights. If desired the indicator **7** and the indicator **33** are also made visible by illuminated dials and, of course, means may be provided for regulating the degree of intensity of illumination of these dials. The motor operating the recording chart, which has not been described because it is conventional, is then set into operation, and if the stylus is provided with a raising finger as is conventional, this must be lowered so that the stylus contacts the chart for recording. The indicator **33** is then adjusted to the maximum pressure beyond which it is not desired to have the apparatus operate for any particular patient.

The control comprising the members **42**, **45**, **46** and **48** may, of course, be mounted upon the control panel of the apparatus. However, I prefer to incorporate them in a remote control hand switch so that the operator may move about and still retain perfect control of the apparatus. The next step is to close the switch member **46**, whereby a circuit is established through the line **41**, the members **42** and **46**, the line **47**, the motor **1**, and the lines **44** and **43**, and the motor **1** is thus set into operation and pressure will be built up in the reservoir **6**. The pressure which is being built up in the reservoir **6** will not be applied to the patient because the valve **15** is open and the patient is thus by-passed. Now, if the switch member **45** is closed a circuit is established through the line **41**, the members **42** and **45**, the line **36**, the contact members **34** and **35**, the line **37** and through the solenoid **24** to the lines **38** and **43**. Thus the solenoid **24** is energized and closes the valve **15**. At this point the green light goes off and the red light comes on, indicating that the patient is being subjected to pressure.

As soon as the stylus **13** has moved a small distance in accordance with the increase of pressure applied to the patient, a holding circuit is completed through the line **41**, the member **42**, the normally closed switch **48**, the line **49**, the contact members **39** and **40**, the lines **50** and **36**, the line **37**, the solenoid **24** and the lines **38** and **41**. It will be clear that as soon as the contact between the members **39** and **40** has been made, the switch member **45** may be opened and the solenoid will continue to be energized through the last described circuit. The switch member **46** need not be kept on continuously because pressure is built up in the reservoir **6** faster than it is passed on to the patient so that the member **46** is preferably a push-button type of switch which may be intermittently actuated to keep the pointer on the indicator **7** at a desired position.

As the stylus **13** moves toward the right pushing with it the member **40**, it reaches the point where the member **40** will abut a projecting portion **35***a* of the contact member **35** and will break the contact between the members **34** and **35**. As was before described, the point at which this contact break occurs may be determined by slight rotations of the plate **30**. As soon as the contact **34**, **35** is broken, the solenoid **24** is deenergized and the valve **15** opens immediately exhausting the patient.

If, before the preset maximum pressure is attained, either or both of the Fallopian tubes opens, there will obviously be an immediate drop in pressure and concurrently the stylus **13** will immediately move toward the left breaking the contact between the members **39** and **40**. Now, since the member **45** was opened as soon as contact has been established between the members **39** and **40**, the solenoid **24** is again deenergized, the valve opens and the patient is immediately exhausted. By these means, discomfort to the

patient is almost completely avoided. It may be noted here that leakage around the canula is, of course, noted by bubbling through the water seal, or by a flashing on of the green light indicating either that the stylus 13 has not been caused to rise sufficiently to make the contact 39, 40, or that having risen and made contact, it has dropped back due to the leak.

The filter 5, previously referred to, is a conventional filter desirable for removing bacteria, moisture and the like from the air. If carbon dioxide is used for the insufflation (its use is sometimes desirable because it is readily absorbed by the system) a tank of carbon dioxide may be connected into the filter at 5a. In connection with the use of a carbon dioxide tank, a reducing valve must be placed between the table and filter because the pressure in the tank is too high. For roentgenological purposes, it is necessary to render the Fallopian tubes opaque. For this purpose I have provided an accessory which is shown in some detail in Fig. 2. This comprises a brass cylinder 51 threaded at both ends and containing a glass cylinder 52. The member 51 preferably has a cut-out portion 51a so that the interior of the cartridge may be observed. In my exemplary device I have threaded a Luer fitting 53 onto the entrance end of the member 51 by means of a threaded flange 54. At the exit end I simply place a Luer fitting 55 over the glass cylinder and clamp it firmly in place by means of the apertured clamping flange 56. Before screwing the member 54 in place, I insert within the cylinder a rubber diaphragm 57 with the edges thereof turned over the rim of the glass cylinder 52. The rubber member is firmly clamped in place by means of the member 54. The portion of the cartridge outside of the rubber member 57 is filled with oil as indicated at 58. From this description it will be clear that if pressure is applied through the entrance fitting 53, the rubber member 57 is inflated and the oil 58 within the cartridge is forced out through the fitting 55, which may be directly or indirectly attached to the canula. Instead of the glass cylinder and brass shell, I may of course use a cylinder made of any material, opaque or not, whereby the construction is simplified, and possibility of breakage eliminated.

I have found that by virtue of the ease of control and adaptability of the apparatus herein described, an entire set of graphs can be made and checked in fifteen minutes or less with little or no discomfort to the patient. I have found that the recording apparatus as checked against a manometer has an accuracy within one-half of one per cent and that the volume required has never exceeded 25 cc. Although there may be occasional discomfort in the region of an opening tube, it is of extremely short duration relieved by the substantially instantaneous exhausting of the apparatus and is rarely followed by subphrenic referred pain, which though of diagnostic value, is not absolutely necessary. I have found that patients do not need to rest following an insufflation and are able to continue their activities immediately.

In making an examination with an opaque medium, the procedure is the same as outlined above except that the oil cartridge is inserted between the canula and the line 10 and the maximum pressure control is raised approximately 150 mm. above insufflation opening (this figure is the approximate oil resistance and can be obtained in any given instance by determining at what pressure oil starts flowing through the canula before its insertion into the uterus). The gas pressure is then gradually increased as with insufflation, the oil noted under the fluoroscope as it enters the uterus and tubes, and the films made as indicated. The fluoroscopy and films can be checked with the graphic record in the chart. My usual procedure is to follow the insufflation immediately with the former procedure without moving the patient from the table. Roentgenological findings are of paramount importance and unless contra-indicated, should always be carried out for diagnoses, although not always necessary in follow-up therapy.

I may also surround the reservoir 6 with heating coils (not shown) in any desired way, and thereby heat the gas to any desired temperature. By then attaching an inflatable member to the tube 10, and inserting the latter in the vagina or other body cavity, I may give heat therapy. This type of treatment is well known in medical practice, and I merely wish to point out the adaptability of my apparatus for such work.

In Fig. 3 I have shown diagrammatically means for determining whether the right or the left tube has opened. The numerals 60 and 61 represent respectively right and left microphones adapted to be held in position on the patient's abdomen in the region of the Fallopian tubes. An amplifier is shown at 62, in which the feeble current generated in the microphone by the sound of an opening tube is amplified to a degree to enable it to operate a visual or audible signal for the right or left sides respectively, as indicated at 63 and 64.

Of course the amplified current may be made to actuate a recording needle in addition to the visual or audible signal, as is well known in the art, for the purpose of making a permanent record as to which tube opened.

It will be understood that modifications in my apparatus may be made without departing from the spirit of my invention and that I do not intend to limit myself otherwise than as pointed out in the claims which follow.

Having now fully described my invention, what I claim as new and desire to secure by Letters Patent is:

1. A diagnostic and therapeutic apparatus for the purposes described, comprising means for producing pressure, means for storing pressure, means for applying said pressure gradually to a patient, and means for automatically discontinuing the pressure on the patient upon the relief of an obstruction to said pressure within the patient.

2. A diagnostic and therapeutic apparatus for the purposes described, comprising means for producing pressure, means for storing pressure, means for applying said pressure gradually to a patient, and means automatically operative to discontinue the pressure on the patient immediately upon the relief of an obstruction to the pressure within the patient, or upon attainment of a predetermined maximum pressure upon the patient.

3. A diagnostic and therapeutic apparatus for the purposes described, comprising means for producing pressure, means for storing pressure, means for applying said pressure gradually to a patient, means for recording and indicating the pressure to which the patient is being subjected, and means operative automatically upon the relief of an obstruction to said pressure within the patient, or upon the attainment of a predetermined maximum pressure within the patient, for

immediately discontinuing the pressure on the patient.

4. A diagnostic and therapeutic apparatus for the purposes described, comprising means for producing pressure, means for storing pressure, means for applying said pressure gradually to a patient, means for recording and indicating the pressure to which the patient is being subjected, means operative automatically upon the relief of an obstruction to said pressure within the patient, or upon attainment of a predetermined maximum pressure, for immediately discontinuing the pressure on the patient, and signal means indicating whether or not pressure is being applied to the patient.

5. A diagnostic and therapeutic apparatus for the purposes described, comprising means for producing pressure, means for storing pressure, means for applying said pressure gradually to a patient, means for recording and indicating the pressure to which the patient is being subjected, means operative automatically upon the relief of an obstruction to said pressure within the patient, or upon attainment of a predetermined maximum pressure, for immediately discontinuing the pressure on the patient, and signal means indicating whether or not pressure is being applied to the patient and remote control means for said apparatus.

6. A method of treating pelvic pathology involving stricture of the Fallopian tubes in the female, which includes the steps of subjecting said tubes to a gradually increasing pressure, and causing the attainment of a predetermined maximum pressure, or the opening of one or both of the tubes, to automatically discontinue the pressure on the tubes.

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