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H. L. ROBINSON

3,482,564

DIAGNOSTIC DEVICE

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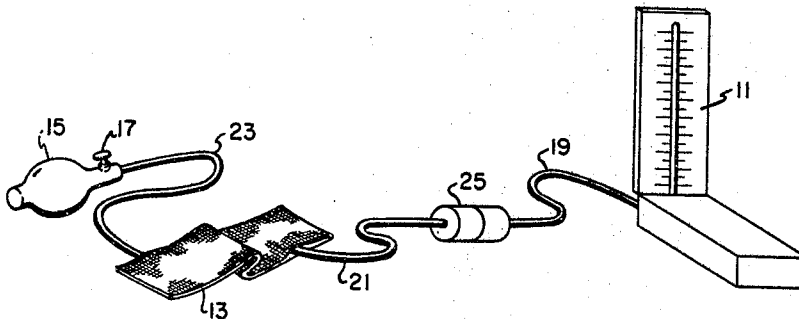


Fig. 1

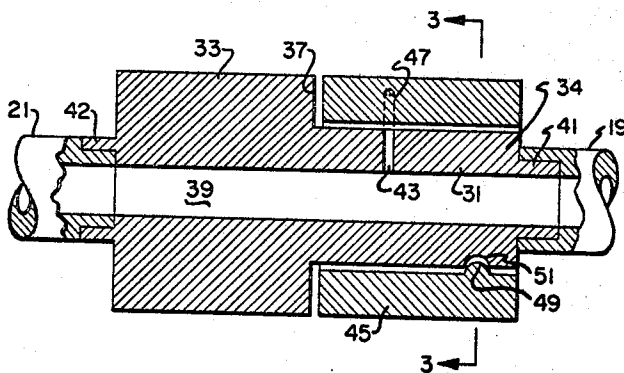


Fig. 2

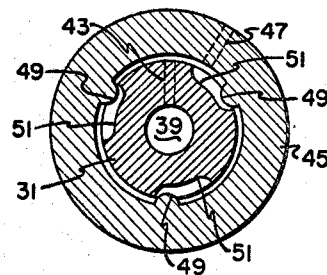


Fig. 3

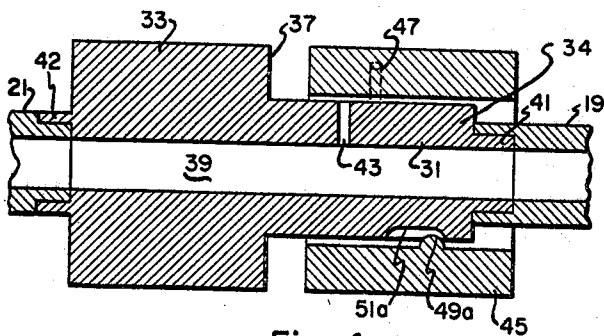


Fig. 4

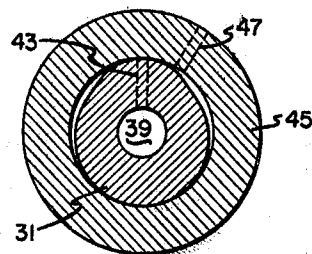


Fig. 5

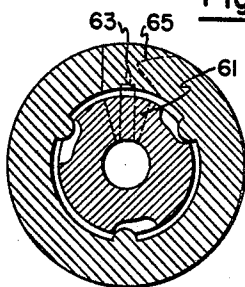


Fig. 6

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DIAGNOSTIC DEVICE

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9 Claims

ABSTRACT OF THE DISCLOSURE

A device for measuring muscular fatigue comprising an "on-off" valve disposed in a closed system between a manometer and an air bulb of a sphygmomanometer where air pressure in the system is built up to a pre-selected valve pressure at which the "on-off" valve is then opened, and the patient squeezes the air bulb in an attempt to maintain the pressure whereby the patient's capability to maintain the pressure may be ascertained by observation of the manometer to determine presence of organic fatigue and more specifically myasthenia gravis.

BRIEF SUMMARY OF INVENTION

Recently the ergograph was developed to aid in the diagnosis of myasthenia gravis. This device comprises an air bulb operatively connected to a tracing device. The patient manually squeezes the bulb and the tracing device records the impulses graphically. Although the resulting tracing provides an objective measurement of the rate of muscle fatigue, it is not of general use because of the need to purchase a special piece of equipment of limited use.

It is an object of this invention to provide a simple device for diagnosing organic fatigue.

It is a further object of this invention to provide a means by which, by a single, inexpensive modification of the conventional physician's sphygmomanometer, there is readily obtained an objective measurement of organic fatigue.

These and other objects of this invention are achieved by a device which comprises a closed system having as essential elements thereof (1) a cyclic, manually-operable pump for introducing air into the system, thereby increasing the internal pressure of the system, such as an air bulb, (2) a manometer for measuring the internal pressure of the system, and (3) intermediate said pump and said manometer a valve adapted to be substantially instantaneously opened from a closed position to a fully opened position, hereinafter referred to as an "on-off" valve, which in the opened position permits the escape of air from the system. In a preferred embodiment, the main elements of pump and manometer are supplied by the conventional physician's sphygmomanometer. In such a system, which has a pneumatic cuff intermediate the pump and the manometer, the valve employed in accordance with this invention is preferably located at a position intermediate the cuff and the manometer, thus providing an air reservoir between the pump and valve to reduce pressure fluctuations resulting from the operation of the pump.

BRIEF DESCRIPTION OF DRAWING

The apparatus of this invention and its mode of use are more fully described hereinbelow in connection with the appended drawings, of which FIGURE 1 represents a schematic diagram of a sphygmomanometer adapted in accordance with this invention; FIGURE 2 is a longitudinal sectional view of one embodiment of a preferred on-off valve employed in accordance with this inven-

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tion; FIGURE 3 is a cross-sectional view of the preferred on-off valve taken along line 3—3 of FIGURE 2; FIGURE 4 is a longitudinal sectional view of an alternative form of on-off valve for use in this invention; FIGURE 5 is a cross-sectional view of a preferred embodiment of the preferred form of on-off valve; and FIGURE 6 is a modification of FIGURE 3 disclosing an alternative but less preferred form of on-off valve for use in this invention.

DETAILED DESCRIPTION

With reference to FIGURE 1, the apparatus of this invention comprises manometer 11, pneumatic cuff 13, bulb 15, needle valve 17, flexible tubes 19, 21 and 23 and on-off valve 25.

With reference to FIGURES 2, 3, and 4, a preferred on-off valve useful in accordance with this invention comprises generally cylindrical body 31. The cylindrical body has two sections, 33 and 34. Section 33 preferably but not essentially has a larger diameter than section 34. Body 31 is provided at its extremities with outwardly extending projections 41 which are adopted to be tightly received in ends of tubes 19 and 21, for example, by a force fit or any suitable connecting means whereby to provide airtight connections. Body 31 is provided with an axial air passage. When projections 41 are received in the tube ends 42, passage 39 is in registry with the tube openings. Provided in section 34 of body 31 is a second or vent, passage 43 communicating between axial passage 39 and the outer extremity of section 34. Rotatably mounted on section 34 of body 31 in close relationship is a rotatable collar 45, preferably having an outside diameter which is the same as the outside diameter of section 33. Thus, the cylindrical outer wall of collar 45 is in substantial alignment with the outer cylindrical wall of section 33 of body 31. Collar 45 has formed therein a through radial passage 47. Upon rotation of collar 45 about its longitudinal axis, air passage 47 can be brought into and out of registration with air passage 43 in section 34 of body 31. When air passage 47 is in registry with air passage 43, air under pressure contained within the system can escape.

With specific reference to FIGURES 2 and 3, collar 45 is rotatably fixed to body 31 and the position and extent of rotation of collar 45 are desirably fixed by suitable means of a type described herein. A preferred means for effecting this purpose comprises at least one and more preferably, at least two projections or knobs 49, formed integral with and extending from the inner cylindrical wall of collar 45. Knobs 49 are received in arcuate grooves 51 formed in the outer cylindrical wall of section 34 of body 31. The relative positions of said grooves, projections and passages are such that collar passage 47 rotates in a plane passing through the longitudinal axis of vent passage 43. The groove 51 is so configured that when knobs 49 engages one edge of the walls in section 34 which defines grooves 51, air passage 47 is in axial alignment with passage 43 and when the other edge is engaged by knob 49 the air passages are not in registry. It is of course, to be understood that alternatively, knob 49 may be provided on the outer wall of section 34 and the rotatable collar 45 can be provided with grooves 51 which receive the knobs on its inner cylindrical wall.

With particular reference to FIGURE 4, in an alternative embodiment, collar 45 instead of being rotatably mounted on section 34 is slidably mounted thereon. In this modification, the position and degree of slidable movement of collar 45 are fixed by knobs 49a on the inner wall of collar 45 (or outer wall of section 34). Knobs 49a are received in longitudinal grooves 51a formed in the outer wall of section 34 (or inner wall of collar 45).

The longitudinal grooves 51a permit movement of collar 45 in a longitudinal direction but preclude rotatable movement of collar 45. Thus, passage 47 is brought into alignment with passage 43 by longitudinal movement of collar 45.

In either embodiment, collar 45 is sufficiently closely fitted to section 34 of body 31 to provide an air-tight seal for vent passage 43 when in the positions shown in FIGURES 3 and 4, i.e. when air passages 43 and 47 are not in alignment. As illustrated in FIGURE 5, a modified view of FIGURE 3, an especially good seal is obtained by providing body 31 with an oval cross-section having its major transverse axis coincident with vent passage 43, providing collar 45 with a cylindrical inside surface having a diameter intermediate that of the major and minor transverse axes of section 34, and constructing collar 45 from a slightly elastically deformable material, such as polyethylene or the like, whereby collar 45 is stretched along said major transverse axis of section 34 to provide an air-tight seal. This modification, although specifically shown in combination with a rotatable collar, is obviously useful with the slidable collar 45 illustrated in FIGURE 4.

The external configuration of the valve, i.e., the shape of section 33 and the outside of collar 45, is not critical, and it can be cylindrical or prismatic in shape. A preferred shape is that of the octagonal prism.

With reference to FIGURE 6, a modified view of FIGURE 3, vent passage 43 of FIGURES 2 and 3 is replaced by spring-loaded valve means indicated generally by dotted lines at 61 having valve stem 63, such as a valve of the type commonly employed in automobile tires; and collar passage 47 is enlarged and contains valve-stem-engaging lip 65. Upon rotation of collar 45 from the closed to the open position, for example, in a counter-clockwise direction as shown, lip 65 engages and depresses stem 63, thus permitting the escape of air from within the system. The use of such a valve system may also be employed in combination with a slidable collar.

Regardless of the valve system employed, the resistance to air flow offered by the escape passage should be such that, when the apparatus of this invention is employed in the test as hereinafter described, the escape rate of contained air will (1) not be substantially less than the rate at which air can be supplied to the system by the operation of pump 15 over a relatively short initial period, and (2) be greater than the rate at which air can be supplied to the system by pump 15 over the total test period. Moreover, the air escape rate should be such that the test will be completed within a reasonable time period, and yet be of sufficient duration to permit a reasonably accurate determination of fatigue. In general, an escape rate such that the test, when performed by a normal patient, will be completed within about two to about three minutes is sufficient. In the preferred valve form, as depicted in FIGURES 2 and 3, it has been found that satisfactory results are obtained when vent passage 47 has a diameter in the range of from about $\frac{1}{64}$ inch to about $\frac{1}{16}$ inch.

With reference primarily to FIGURE 1 and incidentally to FIGURES 2, 3 and 4, the apparatus of this invention is employed as follows:

With needle valve 17 open and on-off valve 25 closed, i.e. wherein air passages 43 and 47 are not in registry, the pressure in the system is increased to a predetermined level, for example, 200 millimeters, as determined by manometer 11, by the operation of bulb 15. The patient is instructed to pump bulb 15 and attempt to maintain the original pressure within the system. Simultaneous with the first pumping cycle, on-off valve 25 is opened by moving collar 45, thus aligning passages 43 and 47 and allowing the contained air to escape. The pumping of bulb 15 is continued until the pressure falls to a predetermined level, for example, 100 millimeters.

In a healthy patient, the onset of fatigue is delayed. Thus, he will be able to supply air to the system at a rate approximating the rate of the escape of air through on-off valve 25. However, as fatigue sets in, the rate at which air is introduced to the system will fall below the escape rate, resulting in a decrease in system pressure, as indicated by manometer 11. In contrast, a patient afflicted with myasthenia gravis experiences a rapid onset of fatigue, with a corresponding rapid pressure drop. Thus, the myasthenic patient more rapidly reaches the second predetermined pressure level. Accordingly, the extent of organic fatigue is indicated by, and is inversely related to, the duration of the test, which may be measured in terms of elapsed time and/or the number of pumping cycles effected as the pressure drops from the first to the second predetermined level.

In addition to diagnosing organic fatigue and more particularly, myasthenia gravis, the device of this invention may be employed to follow the course of treatment of this disease, for example, by treatment with neostigmine bromide. Thus, during the course of treatment the patient can be subjected to the diagnostic test of this invention to determine whether an improvement, i.e. an increase in the number of cycles, results from the prescribed course of treatment.

A particularly salient feature of the present invention is that it is capable of being operated routinely by a technician. Observations can be readily made routinely and quickly by the technician on a large group of subjects and the results can be then reported to a physician for his interpretation.

I claim:

1. In a closed air system of the sphygmomanometer type having a pneumatically-actuated manometer connected to a pneumatic cuff, a manually operable pump connected with the pneumatic cuff and a first valve means associated with said pump, the improvement comprising:

second valve means operable to permit escape of contained air from the system at a rate not less than the rate at which air can be supplied to the system by said pump over a short period of time and at a rate greater than air can be supplied to said system over a longer period of time for testing the presence of organic fatigue in a patient,

said second valve means connected intermediate the pneumatic cuff and the manometer.

2. The device as claimed in claim 1 wherein said second valve comprises a generally cylindrical body having a first, axial passage communicating with said manometer and said cuff and a second, vent passage communicating with said axial passage and the surface of said body and means for substantially instantaneously opening and closing said second passage.

3. The apparatus comprising a closed system having as essential elements thereof (1) pneumatically-actuated manometer for determining the pressure within the system and (2) a cyclic, manually-operable pump for increasing the pressure in the system supplied by a sphygmomanometer having a pneumatic cuff intermediate said manometer and pump, and (3) a valve located at a position intermediate said manometer and said cuff and adapted to be substantially instantaneously opened from a closed to a fully opened position, thereby permitting the escape of contained air from the system at a rate not less than the rate at which air can be supplied to the system by said pump over a short period of time and at a rate greater than air can be supplied to said system over a longer period of time, said valve comprising a generally cylindrical body having a first, axial passage communicating with said manometer and said cuff and a second, vent passage communicating with said axial passage and the surface of said body and means for substantially instantaneously opening and closing said second passage, and wherein said means for opening and closing said second passage comprises a generally cylindrical movable

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collar having a collar passage communicating between the inner and outer surfaces of said collar and being alignable with said vent passage of said body on movement of said collar, said collar being sufficiently closely fitted to said body to provide an air-tight seal for said vent passage when said vent and collar passages are not aligned.

4. The device as claimed in claim 3 wherein said body has an oval cross section with its major axis coincident with said second passage and said collar is constructed of a slightly elastically deformable material and has a cylindrical inner surface having a diameter intermediate the major and minor axes of said body.

5. The device as claimed in claim 3 wherein the position and extent of movement of said collar are fixed by means of at least one projection on the surface of one of said body and collar which rides in a groove in the surface of the other of said body and collar.

6. The device as claimed in claim 3 wherein said collar is rotatable about the axis of said body.

7. The device as claimed in claim 3 wherein said collar is slidable along the axis of said body.

8. A method for measuring organic fatigue in a patient comprising the steps of:

- providing an enclosed air system,
- supplying air to the system by way of a manually operable pump,
- measuring air pressure in the system,
- providing a controlled opening in said system when a preselected pressure value in the system is attained,
- and

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then allowing the patient to manually operate the pump to maintain the existing preselected pressure value, and observing the air pressure being measured to determine the extent of the patient's organic fatigue.

9. A method according to claim 8 including the step of:

regulating the controlled opening so that the rate of escape of air contained in the system is not less than the rate at which air can be supplied to the system by operation of the pump over a relatively short initial period and at a rate greater than air can be supplied to said system over a longer period of time.

References Cited

UNITED STATES PATENTS

505,745	9/1893	Barclay	272—68
1,433,679	10/1922	Fisk	128—2.05
1,644,824	10/1927	Fedde	128—2.05
2,507,858	5/1950	Kegel	128—2
2,624,334	1/1953	Epstein	128—2.05
3,030,945	4/1962	Clark	128—2.05
3,254,671	6/1966	Berliner	128—2.05 XR

L. W. TRAPP, Primary Examiner

U.S. Cl. X.R.

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