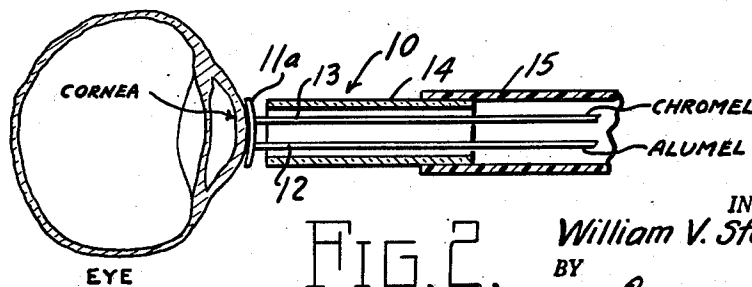
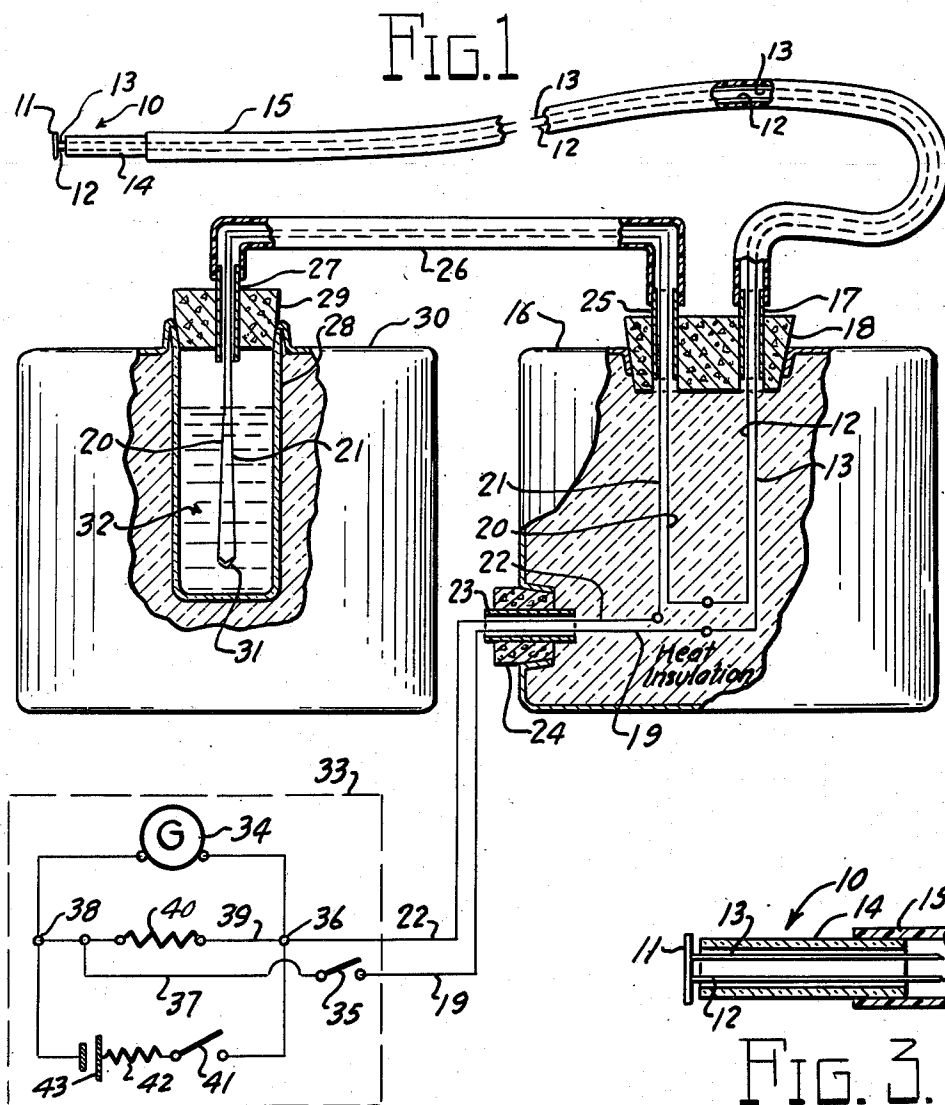


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 APPARATUS FOR THE DIAGNOSIS AND THE CONTROL
 OF TREATMENT OF DISEASES OF THE EYE
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APPARATUS FOR THE DIAGNOSIS AND THE
CONTROL OF TREATMENT OF DISEASES
OF THE EYE

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This invention relates to a method for diagnosing and controlling the treatment of diseases of the eye and to apparatus for carrying out of the method of the invention.

It is, of course, well known that tissue injury, such as that accompanying infection, or other injury, is always accompanied by the release of histamine from the tissue cells which causes a local dilatation of the minute blood vessels, a local increase in the permeability of the capillary walls and a dilatation of the neighboring arterioles resulting from local nerve reflex. All of these result in an increase of blood to the injured area frequently apparent as an inflammation, a swelling, or similar indication. These manifestations of injury are accompanied by resulting changes in temperature of the tissues affected.

It is also known that the temperature of the eye at any time results not only from its pathological condition but from any variants such as the ambient temperature, rate of flow of tears, humidity of the surrounding air and thus the evaporation of the tears, and the blink rate.

The concept of the instant invention thus includes not only the realization that comparisons between the temperatures of the eyes are indicative of the condition of the eyes and that the change in the temperature of an eye over a period of time is indicative of the improving or deteriorating condition of that eye but also the concept of apparatus by means of which such temperatures can be accurately measured.

It is, therefore, the principal object of this invention to provide a method by means of which accurate diagnosis of the presence of disease in the eye can be achieved.

It is another object of this invention to provide a method for the rapid determination of the efficacy of an adopted treatment for a diseased eye.

In the past a physician was forced to depend upon visible indications of the effectiveness of the treatment technique adopted, for example, injections of a selected antibiotic, and frequently a several day period had to elapse before sufficient change in the visible condition of the eye took place for the physician to determine whether or not the treatment was effective. Unfortunately, in instances where the wrong technique had been adopted, the disease might have progressed alarmingly before the physician had any reason or any indication to change the method of treatment. In contrast, through the practice of the instant invention, indications of the effectiveness of the treatment technique are available within a matter of relatively few hours.

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It is another important and concurrent objective of this invention to provide apparatus embodying its fundamental concept, i. e., that the temperature of the available surface of the eye, the cornea and exposed portion of the sclera accurately reflect the physiological condition of the eye and can be depended upon as an accurate indication of the relative condition of either eye over a period of time and of the comparative conditions of the two eyes at any time and through a period of treatment.

As mentioned, the discovery that the temperature of the cornea and/or the sclera is highly indicative of the condition of the eye has made feasible the invention of the apparatus and treatment and diagnostic method embodying the invention. Were the temperatures of these two areas of the eye surface not indicative, measurement of the temperature of other portions of the eye would require techniques such as surgery or a similar violent treatment which, in themselves, might affect the temperatures being measured.

The procedures and apparatus embodying the invention which are set forth in the specification that follows may be more fully understood by reference to the drawings attached hereto, in which:

Fig. 1 is a schematic showing, with portions of the useful apparatus shown in section, and including a schematic wiring diagram of apparatus embodying the invention as assembled for the carrying out of the method of the invention.

Fig. 2 is a greatly enlarged fragmentary view illustrating the portions of the apparatus actually directly applied to the cornea of the eye the temperature of which is being measured.

Fig. 3 is a fragmentary view of a modification of the eye contacting portion of the device.

In describing the clinical technique involved in the practice of the instant invention and in illustrating and describing apparatus embodying the invention, techniques and apparatus for measuring corneal temperature will be explained but the invention is not limited to measuring the temperature of the cornea and the same techniques and apparatus are effective also for measuring the temperature of the exposed portion of the sclera.

In carrying out the method of the invention it is important to eliminate insofar as possible all errors or possibility of errors due to the many factors known to influence eye temperatures. It has been determined, for example, that local anaesthesia brings about practically complete vasodilatation of the peripheral blood vessels thus causing a rise in temperature of the area. The influence of anaesthesia on the temperatures of

the eye being measured must be compensated for by the employment of identical anaesthetizing techniques in each measurement. For example in the practice of the instant invention, the effect may be standardized by the instillation in each case of one drop of, for example, 0.5% "Pontocaine" at the same place in each eye, for example, at "12 o'clock" on the limbus. The patient's lids may then be left closed for a period of one minute to permit absorption of the anaesthetic.

In order to eliminate any error which might result from unnatural blink reflex, the eyes are then opened and, for a period of five minutes, allowed to readjust themselves to reestablish the normal blink frequency.

The rates of evaporation of the eye fluids and of the anaesthetic and the effect of ambient temperature and air humidity on the eye temperatures are controlled by carefully regulating both the temperature and humidity of the air in the room where the measurements are taken. The effect of outdoor temperatures and humidity on the eyes of the patient are standardized by placing the patient in a treatment room with controlled temperature and humidity for a sufficient period prior to the tests for the eyes to respond to the room temperature.

Thus by the careful control of surrounding conditions so as to standardize their effect upon the corneal temperatures of the patients being treated, these sources of error while not eliminated, are standardized so that comparative temperatures taken at different times are based upon the same conditions surrounding the patient.

Because of the high degree of accuracy necessary in the measurements taken, it is important that the effect of all parasitic electro-motive forces should be eliminated as nearly as possible from the measuring apparatus. This is accomplished by insulating the various components electrically and thermally. Again, because of the small temperature changes being measured it is necessary that the measuring components of the apparatus employed should be isolated insofar as possible from the effects of vibration and ambient air temperatures and currents. The means for accomplishing these steps of protection of the apparatus will be set forth in the description of the apparatus that follows:

A measuring apparatus embodying the invention comprises, among other parts, a receiver, generally indicated by the reference character 10, and consisting in a circular (Figs. 1 and 3) or partially spherical (Fig. 2) plate 11 or 11a and conducting wires 12 and 13. The plate 11 may be fabricated from gold foil, for example, 1 millimeter in diameter and 5 microns thick. The two wires 12 and 13 may be wire gauge number 40 (approximately the thickness of a human hair) and made from thermally responsive alloys, for example, those called Alumel and Chromel respectively. The two Alumel and Chromel wires 12 and 13 are welded to the gold leaf receiver plate 11.

In the original experiments the receiver plate 11a (Fig. 2) was so shaped that it could be held in contact with the cornea by surface tension of the tear liquid. At a later date it was discovered that an intimate contact of this kind was not necessary and the receiver plate 11 (Figs. 1 and 3) was made flat so that physical contact, only, was made between the receiver plate 11 and the cornea of the eye. This reduced the small irritation of the application of the receiver to the cornea and simplified the measurement.

Therefore the receiver plate can be made in either curved or plane form with satisfactory results.

The receiver element 10 comprising the contact plate 11 and two lead wires 12 and 13 is mounted by means of a thin glass tube 14 from the open end of which short lengths of the two wires protrude. The glass tube 14 thus serves as a handle by means of which the contact plate 11 can be placed against the cornea and also as an insulator to prevent the temperature of the hand of the physician from influencing the temperature of the eye being measured.

The glass tube 14 is inserted in the open end of a flexible plastic tube 15 through which the two lead wires 12 and 13 are led to a thermally insulated container 16. The plastic tube 15 is fitted over a short glass tube 17 which may, for example, be inserted in a stopper 18 for closing the upper end of the container 16. In the interior of the container 16 the two lead wires 12 and 13, for example, Alumel and Chromel or iron and constantan respectively, are electrically connected to other lead wires 19 and 20. The wire 20 is one of a pair of lead wires 20 and 21 which, in this instance, also are Alumel and Chromel respectively, so that the Alumel lead wire 12 is connected to the Alumel lead wire 20. The Chromel lead wire 21 is connected to a conductor 22 which is paired with the conductor 19 and led out of the container 16, for example, through a glass tube 23 in a stopper 24. The two conductors 19 and 22 can be fabricated from fine copper or other conducting material and electrically insulated only (electrical insulation is not shown in the drawings).

The two thermocouple wires 20 and 21 are led out of the insulated container 16 through a second glass tube 25 in the stopper 18 and through a protective plastic tube 26 in the end of which the glass tube 25 is inserted and then through a glass tube 27 over which the other end of the plastic tube 26 is fed. The glass tube 27 enters a thermally insulated liquid containing flask 28 through its stopper 29. The flask 28 is enclosed in a mass of Thermal insulation contained in an enclosure 30.

The two thermocouple wires 20 and 21 are joined as at 31 inside the flask 28 and beneath the surface of a constant temperature bath 32 maintained therein.

The bath 32 is maintained in the flask 28 for the purpose of establishing a constant reference temperature for the thermocouple junction at 31. This bath, for example, may consist in a saturated solution of sodium sulfate decahydrate crystals ("Glauber's salts") and sodium sulfate anhydrous in the well known constant temperature relationship. This bath is particularly good because it exists at the temperature of 32.383° C., which is quite close to a general average of the corneal temperatures. Thus the deflections in any measuring instrument will be relatively small.

The conducting wires 19 and 22 are led to an instrument box 33 containing an ultra sensitive galvanometer 34 which should be responsive to very small changes in E. M. F. resulting from small changes in temperature at the measuring thermocouple on the cornea. For example, the galvanometer may be of the type having a sensitivity of, say, .05 microvolt per millimeter.

The lead 19 is connected to one side of a normally open switch 35 and the lead 22 connected to a junction 36. The other side of the switch 35 is connected by a lead 37 to a junction 38.

The junctions 36 and 38 are connected by a lead 39 in series with a resistance 40. The galvanometer 34 is connected to the junctions 36 and 38 in parallel with a switch 41, resistance 42 and cell 43 that are connected together in series to the junctions 36 and 38.

The cell selected should be constant in E. M. F. and in practice it has been found that a mercury cadmium amalgam cell of the unsaturated type having a E. M. F. of slightly more than 1 volt is effective.

Although the gold leaf contact disk 11a, constructed as shown in Fig. 2, is effective in detecting small changes in temperature, early experimentation showed that it was too fragile mechanically to permit sterilization. In further experiments using the apparatus embodying the invention, the gold leaf was replaced by a platinum disk (as shown in Figs. 1 and 3) approximately 2 millimeters square and 0.0006 millimeter thick. Experiments have shown that platinum, as a material for the construction of the disk 11, is no more irritating to the cornea of the eye than gold foil and its greater strength due to its thickness and size facilitates handling the apparatus during examinations and experiments. Success also has been achieved using a receiver made of gold .008 cc. thick and approximately 6 mm. in diameter, these dimensions and the others being merely illustrative.

Because of the very small electromotive forces to be measured, it is essential that all source of error should be eliminated from the electrical circuit itself. For this reason the circuit includes the cell 43 and switch 41 arranged in parallel to the leads from the thermocouple corneal temperature measuring portions of the device. When the switch 41 is closed a known E. M. F. from the cell 43 is applied across the galvanometer. This checks the accuracy of the galvanometer and establishes any constant deflection due to galvanometer lag which can subsequently be balanced off in the recording of temperatures. The second step in eliminating errors due to the electrical nature of the apparatus consists in immersing the corneal temperature receiver, i. e., the thermocouple junction consisting in the ends of the wires 12 and 13 and the plate 11, in the constant temperature bath 32 with the thermocouple junction at 31. There is, therefore, no difference in temperature between the two thermocouple junctions and the deflection of the galvanometer thus is directly established by the known temperature of the bath 32 and the resistance of the electrical elements in the circuit. This deflection is compared with the deflection of the galvanometer under the known E. M. F. from the cell 43. It is then possible to calculate a constant K for the apparatus, according to the equation

$$t = K \frac{d_2}{d_1}$$

In this equation t equals the temperature of the corneal contacting thermocouple junction at the plate 11, K the constant for the apparatus, d_2 the deflection of the galvanometer with both junctions in the constant temperature bath and d_1 the deflection of the galvanometer when connected to the cell 43.

With the reference junction at 31 maintained at a constant temperature in the bath 32 and knowing the constant K established for the apparatus as above, the scale on the galvanometer 34 can be so adjusted and established that galvanometer deflections d_2 are directly proportional

to, and can be directly indicated as, temperatures at the corneal contacting junction on the plate 11.

The procedure for taking the temperature of an eye to be tested consists in first accommodating the patient to the temperature and humidity of the examination room in order to eliminate the effect of temperature and humidity elsewhere on the temperature of the particular patient's eyes. The two eyes are then anaesthetized by the application of a carefully measured amount of anaesthetic applied to a particular point in each eye, for example as mentioned above 1 drop of 0.5% "Pontocaine." The patient's eyes are then maintained closed for a period of 1 minute and rested open for 5 minutes to reestablish the normal blink period. The measuring thermocouple junction comprising the plate 11 is then placed against one of the patient's eyes and the temperature recorded. As quickly as possible it is then placed against the other of the patient's eyes and that temperature is recorded.

By many experiments it has been determined that the average corneal temperature for most people is 33.6° C. If both of the eyes are reasonably close to this average it is probable that neither of the eyes is diseased but the two eyes will not have the same temperature in the majority of cases. Experimentation and testing have revealed that the temperatures of two normal eyes are likely to vary as much as .1° C.

If the temperature of one eye is found to be higher than that of the other by an amount substantially greater than .1° C., for example, but as little as .5° C. or less, or as much as 4 or 5° C., it is a conclusive indication that that one of the eyes having the higher temperature is diseased. Where a substantial temperature difference between the two eyes is thus detected, the physician is able to immediately diagnose a diseased condition even if other manifestations of disease such as inflammation or swelling or high tear flow, etc., are not yet present.

The physician then makes additional examinations, tests and studies of the usual nature in an attempt to positively identify the nature and cause of the difficulty and may reach a conclusion based upon his knowledge of the subject matter as to the particular disease from which the patient is suffering. Experimentation has, indeed, indicated that the degree of difference between the temperatures of the two eyes is in itself indicative of the nature of the difficulty in the diseased eye and a large variation can be interpreted as resulting from a cause different from that which produces a much smaller variation.

In any event the physician then determines upon a method of treatment, for example, he may inject a selected antibiotic into the patient's blood stream. Surprisingly, in as little as 24 hours time, if the medication or treatment is proper for the disease present, the temperature of the warmer eye will drop appreciably. Under these conditions continued treatment over subsequent days will be reflected in a continuing drop in temperature. When the temperature of the diseased eye approaches that of the normal eye, the physician can determine that a cure is almost effected even though other manifestations of the diseased condition may have disappeared long before the temperature of the eye has approached normal (the temperature of the unaffected eye plus or minus, for example, .1° C., depending upon the individual).

If, on the other hand, the differential between

the temperatures of the two eyes has remained the same or has increased within the first 24 hours after selected treatment, it is conclusive that the method of treatment chosen was inappropriate for the disease present. The physician thus is given early warning that his treatment is not effective and he can change treatment before a sufficient time passes for the eye to have been much more seriously injured by the disease.

In the event that both eyes are diseased at the time of the original measurement, the physician's attention to the condition will be established by reason of an appreciable difference in eye temperature above the normal of 33.6° C. and probably by a differential between the temperature of the two eyes of the patient greater than that normally to be expected, it being highly unlikely that both eyes would be affected to the same extent by a disease even though both eyes were diseased. In proceeding with the indicted treatment both eyes should respond and the response be indicated by a drop in temperature of both eyes within a short period.

As illustrative of the technique and results the following cases are included.

Case I

A white female patient, age 44, and apparently in normal health, had complained of blurred vision in the left eye for several weeks. Several competent ophthalmologists had examined the eye by routine medical examination means and found no indications of disease, in fact, had found the eye entirely normal. By vision tests on the first day the right eye was found 20/20 and the left eye 20/30. The patient's corneal temperatures were taken by use of apparatus embodying the invention and in accordance with the method outlined above the following temperatures were indicated: right corneal temperature 33.4° C., left corneal temperature 33.9° C. While these two temperatures were reasonably close to the average temperature of 33.6° C., the difference of .5° C. between the two eyes indicated disease in the left eye. The patient, therefore, was given a complete and thorough physical examination, including blood chemistry, urinalysis, tubercular skin tests, teeth and chest X-rays, mass agglutination and head X-rays. X-rays of the sinus areas revealed a slight clouding of the frontal, ethmoid, and maxillary sinuses. From these indications the patient was placed on a treatment of chloramphenicol (antibiotic), triple sulfonamides, foreign proteins and ephedrine nasal packs.

Under normal conditions of treatment without the use of apparatus and methods embodying the invention, a period of several days would then have had to elapse before detectable response to the treatment was apparent. Indeed, three days later the vision in the diseased eye had dropped to 10/200 and there was one diopter of papilloedema. These results would appear to indicate that the treatment adopted was not correct. Examination through the use of apparatus of the invention, however, revealed that the temperature of the diseased eye had started to drop and the difference between the temperatures of the eye was considerably smaller. Shortly thereafter the eye began to clear, proving that the treatment continued as indicated by the measured reduction in difference between the temperatures of the normal and diseased eye was effective. On the eleventh day after first examination the corneal temperature of the left eye had dropped to 32.3°

C. and the right eye had dropped to 31.9° C. This substantial reduction in the temperature of each eye indicated reduction in the general diseased condition and showed a difference of only .4 C. between the two eyes. By the twentieth day after treatment the vision in the two eyes had returned to the original right 20/20 and left 20/30. The difference between the corneal temperatures had dropped to .3° C. All medication except the foreign protein was discontinued and by sixty days after treatment commenced the temperatures of the two eyes differed by only .07° C., indicating a complete cure. All therapy was then discontinued.

The advantages accruing from the use of the apparatus embodying the invention in the case detailed above were two. First, in the face of several examinations none of which revealed any abnormality in the eyes, the original difference of .5° C. was sufficient to require extensive examinations not normally resorted to to determine any diseased condition. Second, in the face of an apparent complete cure as of the time when the vision had returned to normal, therapy was continued because of the still substantial difference in temperatures of the two corneas until a complete cure was effected sixty days after first examination.

Case II

An even more forceful illustration of the effectiveness of the method of the apparatus in detecting and controlling disease of the eye appears in the case of a white female, age 52, who was first examined and found to have corneal temperatures in the right eye of 35.4° C. and the left eye 31.1°. This difference of 4.3° C. indicated a very severe infection. At the same time the vision in the eyes was right eye 20/200, left eye 20/20. Treatment was started at once. By the fourth day the temperature in the affected eye had dropped appreciably, the difference between the two eyes being only .7° C. By approximately the fiftieth day after treatment commenced, the vision in the two eyes was measured at right eye 20/50 and left eye 20/20. The eyes appeared to be clear and normal and the pain had completely disappeared. Under normal conditions all treatment probably would have been stopped at this time, but through the use of apparatus embodying the invention it was found that the difference in corneal temperatures was still .43° C., which was too great for normalcy. Intensive treatment, therefore, was continued for an additional period of fifteen days. At the end of that time the corneal temperature difference had dropped to .02° C. and upon examination vision was right eye 20/40 and left eye 20/20.

Apparatus embodying the invention, including the concept of diagnosis and indication of treatment effectiveness through the use thereof, for the measurement of corneal temperatures constitutes the subject matter of the present invention which is set forth in the subjoined claims.

I claim:

1. Apparatus for determining the pathological condition of an eye comprising, in combination, a galvanometer; a thermocouple connected thereto, said thermocouple having one junction consisting in a small thin metallic plate adapted to be contacted to the normally exposed surface of an eye under examination and a pair of different thermally responsive conductors mechanically secured adjacent each other to said plate, and a second junction of a second pair of similar conductors; a vessel for maintaining a con-

stant temperature bath in which said second junction is maintained; a thermally insulated box into which the non-junction ends of both of said pairs of conductors are maintained, a like one of each of said pairs of conductors being electrically connected; and electrical leads from the other like ones of each of said pairs of conductors to said galvanometer.

2. Apparatus according to claim 1 having a source of known E. M. F. electrically connected in parallel with said thermocouple leads and switching means for alternatively connecting said source of known E. M. F. and said thermocouple to said galvanometer.

3. In a thermocouple actuated temperature measuring apparatus having a galvanometer for indicating the thermocouple potential, the improvements consisting of a second thermocouple constructed from two materials identical to those of the first said thermocouple, means for maintaining the junction of said second thermocouple at a constant reference temperature, the junctions of said first and second thermocouples having one pair of like wires connected to each other and the other pair of like wires in series with lead wires to said galvanometer, and a thermally insulated enclosure for the connections between the first said pair of like wires and the connections between the other of said pairs of like wires and said lead wires.

4. Apparatus for measuring the corneal temperature of an eye of a patient comprising, in combination, a sensitive galvanometer, a source of known E. M. F., a double thermocouple having two junctions, each thermocouple having a junction consisting in electrically connected ends of two wires of different thermally responsive resistance, one of said junctions being a reference junction, the other of said junctions including a corneal contact disk mechanically and electrically connected to the ends of said wires, means for maintaining said reference junction at a constant temperature, a thermally insulated con-

nection box, galvanometer leads into said connection box, the non-junction ends of one pair of like wires of said thermocouples being electrically connected and the similar ends of the other pair of like wires being connected in series with said galvanometer leads, such connections being located in said connection box and electrical means for alternatively connecting said source of known E. M. F. and said thermocouples in series with said galvanometer.

5. Apparatus for measuring the temperature of the normally available surface of an eye of a patient comprising, in combination, a sensitive galvanometer, a source of known E. M. F., a double thermocouple having two junctions, each thermocouple having a junction consisting in electrically connected ends of two wires of different thermally responsive resistance, one of said junctions being a reference junction, the other of said junctions including a surface contact disk mechanically and electrically connected to the ends of said wires, means for maintaining said reference junction at a constant temperature, a thermally insulated connection box, galvanometer leads into said connection box, the non-junction ends of one pair of like wires of said thermocouples being electrically connected and the similar ends of the other pair of like wires being connected in series with said galvanometer leads, such connections being located in said connection box and electrical means for alternatively connecting said source of known E. M. F. and said thermocouples in series with said galvanometer.

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