

[54] INCONTINENCE MEASUREMENT SENSOR

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[22] Filed: Apr. 23, 1971

[21] Appl. No.: 136,710

[30] Foreign Application Priority Data

Apr. 29, 1970 Great Britain 20,514/70

[52] U.S. Cl. 128/2 R, 128/138 A

[51] Int. Cl. A61b 5/00

[58] Field of Search..... 128/2 E, 2 F, 2 G,
128/2 R, 2.1 R, 2.1 Z, 138 A

[56] References Cited

UNITED STATES PATENTS

3,245,068	4/1966	Wegryn et al.	128/138 A
3,085,566	4/1963	Tolles.....	128/2.1 Z
2,127,538	8/1938	Seiger.....	128/138 A

FOREIGN PATENTS OR APPLICATIONS

1,174,346	12/1969	Great Britain	128/138 A
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236,255	11/1961	Australia.....	128/138 A
673,239	10/1929	France	128/138 A

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[57] ABSTRACT

Urinary incontinence can be evaluated both in respect of frequency and quantity by use of a detector device in the form of a flexible sheet of absorbent material having elongate electrodes supported in it in an interleaved, uniformly spaced array. This device is worn as a diaper and any incontinence will vary and be detectable and measurable by the electrical conductivity of the sheet material between the electrodes. Any undesirable variations in this technique due to compression of the sheet in use can be offset by supporting the electrodes in a waved manner along their lengths and through the sheet thickness, and by quilting the sheet. Other variations due to differing urine salts content can be taken into account by pre-loading the sheet with a salt to give a datum or bias salt level above which such variations are less significant.

6 Claims, 2 Drawing Figures

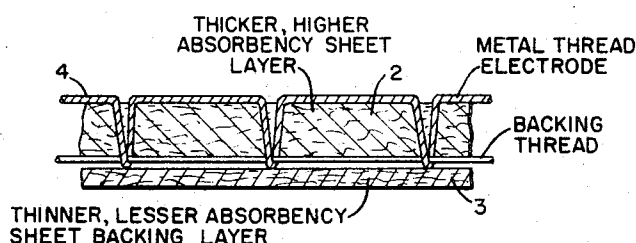


FIG. 1

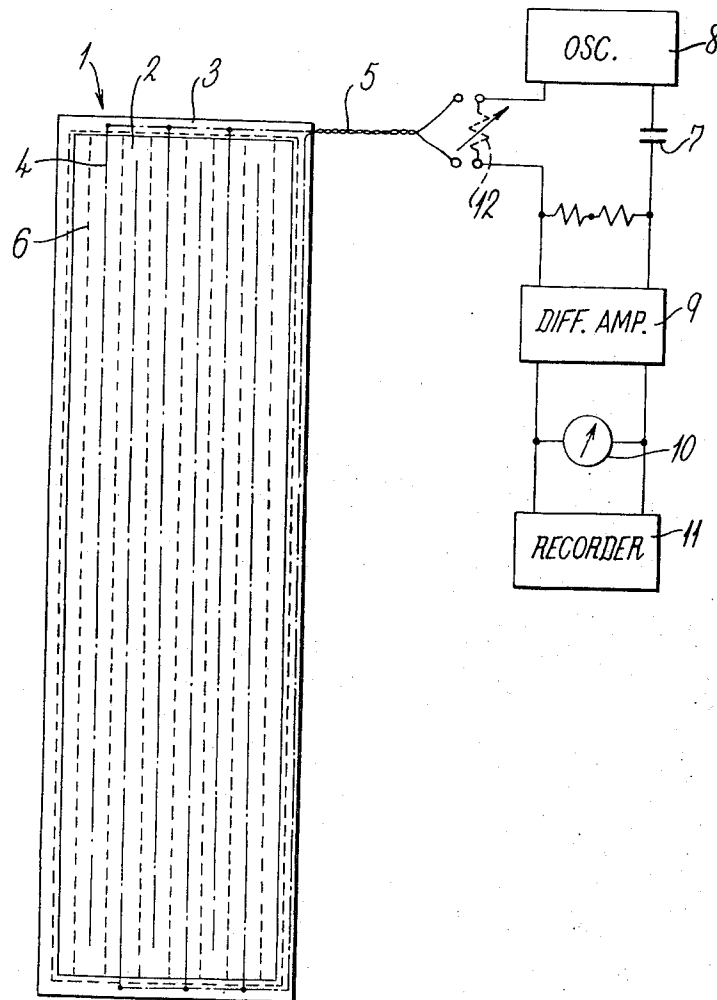
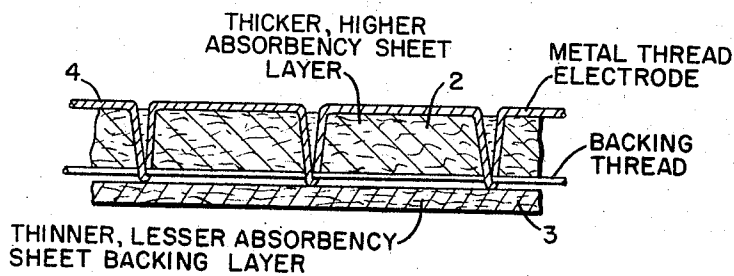


FIG. 2



INCONTINENCE MEASUREMENT SENSOR

Various proposals have been made in connection with the treatment of urinary incontinence. For example, diaper-like devices have been proposed to render the results of such incontinence less inconvenient, mechanically operable devices to be "worn" internally or externally have been proposed whereby such incontinence may be controlled, implantable devices to enhance muscle control by electrical stimulation have also been proposed for urinary incontinence control purposes, and devices to give alarm or shock therapy have been proposed for enuresis.

Most of these various devices are used in practice and they can attain their objects in appropriate circumstances. However, there are different forms of urinary incontinence and the choice of device, or more generally the treatment to be adopted for an incontinent patient should naturally depend on the form of incontinence at hand. There is, though, often difficulty in deciding on what form of incontinence is to be dealt with. This difficulty arises from the fact that one of the main factors relied upon is the patient's own observations, but the patient, usually being a member of the lay public, cannot be relied upon to observe as accurately as trained personnel.

An object of the present invention is to reduce this area of difficulty by providing a device whereby urinary incontinence can be observed independently, without embarrassment or significant inconvenience to the patient.

To this end, the invention provides, in a more general aspect thereof, a device comprising a flexible sheet of absorbent material having a pair of elongate electrodes supported therein in an interleaved, uniformly spaced array. The electrode array will normally span a major, or at least significant area of the sheet for this purpose each electrode may comprise a plurality of parallel limbs connected at one end to a common terminal conductor, the limbs of the respective electrodes being interleaved in an alternating sequence. Other geometrical configurations, such as interleaved spirals, for example, may be equally suitable.

In use of such a device, it will normally be worn by a patient in the manner of a diaper, although the sheet can also be appropriately located in a cot or bed, and the two terminal conductors are subjected to a low voltage alternating current. Then, when urine loss occurs, a zone of the electrode area becomes moistened and the resultant change in electrical conductivity can be detected, and indicated and/or recorded, by suitable instruments coupled to the device. It is preferable to record signals representing both the time (to denote frequency) and magnitude of urine loss, as by a pen recorder or other suitable instrument. It is also preferable that a record be made simultaneously concerning the physical attitude or activity of the patient at least when urine loss occurs. This function can be carried out simply by an observer in conjunction with the first-mentioned instrumentation, although it may be desirable to add further instrumentation responsive to a strain gauge or other form of transducer connected to the patient to indicate activity.

In any event, in a more particular aspect the invention provides urinary incontinence measuring apparatus comprising a device together with energisation means and instrumentation as described above. It is to be noted that such a device and associated energisation

means and instrumentation can be coupled by "leads" where complete freedom of mobility for the patient is not required, while the coupling can be by radio telemetry when complete freedom is required (to reduce the risk of accident involving leads where the patient is an infant or sleeping, say), the energisation means being carried with the device together with a suitable transmitter. It may also be possible, as another alternative, for the instrumentation to be carried with the device and energisation means on the patient, the instrumentation comprising a miniature tape recorder, say.

Certain more particular features have been found preferable for the device during development of the invention. For example, it is desirable that the sheet material should absorb and spread liquid in the plane of the sheet sufficiently rapidly to afford a capacity which does not lead to saturation at a level of urine loss which is too low for a more general use of the invention. However, this requirement will normally entail the use of sheet material which is significantly thicker than the electrode material, the latter being relatively thin to give the flexibility and comfort compatible with effective use of the device as an under-garment. This leads to a possible difficulty in that the electrical conductivity between the electrodes may vary for a given level of urine loss as a function of the compression of the sheet which is variable, in turn, in dependence upon patient activity.

This possible difficulty is reduced in a preferred form of the device, representing another more particular aspect of the invention, by supporting the electrodes in a generally cyclically varying waveshape extending along the electrode lengths and through the thickness of the sheet. A suitable manner of obtaining such an electrode waveshape is by sewing the sheet with the electrode material serving as the thread in a conventional stitching mechanism.

It has also been found useful in this same connection to quilt the sheet of the device since this can serve to reduce the effects of variable compression without unduly restricting the desired lateral absorbency of the sheet. Quilting is additionally useful in serving to stabilise the positions of the electrodes in the sense of their mutual spacing, and the quilting is conveniently effected by lines of stitching uniformly spaced between adjacent electrode lengths.

A further difficulty can arise by variation of electrical conductivity with urine salts content. This variation can arise not only between different individuals, but also between different times of the day for a given individual. Magnitudes of variation have been measured which are equivalent to that between a 0.5 percent and 1.5 percent (by weight) aqueous sodium chloride solution, and these can clearly introduce error into any quantitative measure obtained by use of the invention.

In accordance with a further more particular aspect of the invention this last difficulty is reduced by pre-loading of the device with salt in any appropriate manner before use to provide a dry device impregnated with salt whereby signals representing the level of incontinence are effectively biased to a predetermined level which is relatively independent of urine salts content. A suitable pre-loading for this purpose is approximately equivalent to a 5 percent (by weight) aqueous sodium chloride solution saturating the sheet. This level of pre-loading has been found suitable in giving a

satisfactory bias without swamping the signal variations of interest or causing skin irritation.

In development of the present invention to date, devices as described above have been used repeatedly with appropriate cleansing and fresh pre-loading between successive measurement tests. However, it is contemplated that the devices would be made available for more general use as disposable items pre-loaded by the manufacturer.

For a clearer understanding of the present invention, the same will now be described by way of example, with reference to the accompanying drawing which schematically illustrates one form of device and associated instrumentation.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a diagrammatic top plan view of a device constructed in accordance with the present invention; and

FIG. 2 is a vertical cross-sectional view through a portion of the sheet of the device.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

In the drawing the device is denoted at 1 and comprises a multi-layered sheet of cotton mesh 2 of strip form measuring approximately 18×5 ins. The sheet is backed by a layer of nylon cloth 3 which is less readily permeable by liquid than the cotton mesh and serves to assist the lateral spread and absorption of liquid as mentioned earlier.

The electrode array is provided by surgical stainless steel wire, of about 36 gauge, stitched to the sheet parallel to the longitudinal axis thereof in six lengths at equal spacing of about 0.5 in. This wire is denoted by chain lines 4 from which it will be seen that two interleaved electrodes with three limbs each are formed by connecting the associated limbs at opposite ends of the sheet at respectively different conductors of a twin lead 5. The lead 5 is connected to the electrode limb wires by crimping or in any other suitable manner and is held to the sheet by overlapping the backing sheet to provide a stitched marginal tunnel through which the conductors run. The sheet is also stitched longitudinally with thread intermediate to the electrode limbs as denoted in broken line at 6.

The lead 5 is powered at about 30 mV through an

A.C. coupling 7 by a 2Kc/s oscillator 8. The lead is also connected across measuring and recording apparatus including a differential amplifier 9, a meter 10 and a pen recorder 11. The electrode array and sheet act as a variable resistor denoted in broken line at 12 and having a value less than 100 when the sheet is fully saturated in the present example.

We claim

1. A urinary incontinence detector device comprising:
 - a sheet of absorbent material; a dry salt dispersion in said sheet to preload the sheet whereby, when moistened with urine, the natural salt content of urine is not a significant factor in changing the electrical conductance of the sheet; a pair of elongate electrodes connected to said sheet in a uniformly spaced array extending over a major area of said sheet; and terminals for connecting said electrodes to an electrical conductance indicator.
 2. A device according to claim 1 wherein each of said electrodes comprises a plurality of parallel limbs each connected at one end to a common terminal conductor, the limbs of the respective electrodes being interleaved in an alternating sequence.
 3. A device according to claim 1 wherein said electrodes are supported in said sheet in a generally cyclically varying waveshape extending along their lengths and through the thickness of said sheet, which waveshape is of short length compared to the planar dimensions of said sheet.
 4. A device according to claim 1 wherein said sheet is of laminated form comprising a thicker layer of a first absorbent material to enhance the spread of urine through the plane of said thicker layer and thereby act against local saturation therein, a second layer of different absorbent material having a lesser liquid permeability than said first material, said second layer backing said first layer.
 5. A device according to claim 1 wherein said sheet is quilted along lines which are uniformly spaced between adjacent lengths of said electrodes.
 6. A device according to claim 1 wherein said salt dispersion is approximately equivalent in electrical conductance to that of the salt in a 5 percent, by weight, aqueous sodium chloride solution saturating said sheet.

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