UK Patent Application (19) GB (11) 2 160 107 A

(43) Application published 18 Dec 1985

(21) Application No 8520200

(22) Date of filing 26 Oct 1984

Date lodged 12 Aug 1985

(30) Priority data

(31) 8305947

(32) 28 Oct 1983

(33) SE

(60) Derived from Application No **8427112** under Section 15(4) of the Patents Act 1977

(71) Applicant

Astra-Tech Aktiebolag (Sweden), Arstaangsvagen 1A, S-117 43 Stockholm, Sweden

(72) Inventor Stig Lundback

(74) Agent and/or Address for Service

J. A. Kemp & Co.,

14 South Square, Gray's Inn, London WC1R 5EU

(51) INT CL⁴
A61N 1/04

(52) Domestic classification **A5R** 85F1

(56) Documents cited

GB A 2005142

GB 1350368

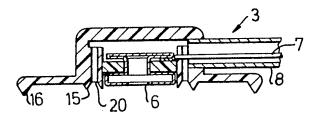
GB 1594214 GB 1575364 GB 1236350 GB 1128329

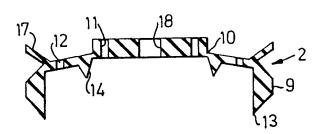
GB 1567961

(58) Field of search A5R

(54) Electrode plate for an ECG electrode

(57) For an electrode intended, for example, for electrocardiogram examinations, and capable of being held in position by suction, consists of a metal or plastics plate whose front contact surface is of silver coated with silver chloride and whose rear surface carries the male portion of a press stud connector allowing the plate to be readily removed and replaced. The front surface is formed with protruding portions 4 to improve skin contact.





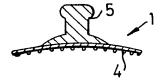
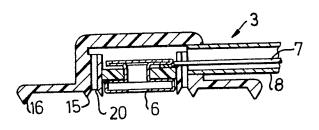
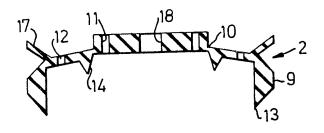


FIG. 1







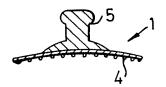


FIG. 1

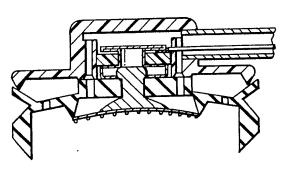


FIG.2

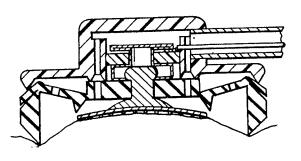


FIG.3

SPECIFICATION

Electrode plate for an ecg electrode

5 The invention relates to an electrode plate for an electrocardiogram (ECG) electrode.

Such anelectrode is known from Austrian Patent Specification No. 248,608. This known electrode is attached through the agency of a vacuum applied 10 through a tube connected to the electrode. A valve, which assists in the application of the vacuum is held closed when the electrode is not attached, opens automatically when applying the electrode, and closes automatically should the electrode fall 15 off. According to one described embodiment, an electrode plate is spring-biassed with the aid of an elastic diaphragm coupled to a surrounding sealing ring. When the electrode plate is pressed against the skin of a patient, a valve opens and a vacuum 20 is applied to a cavity extending around the electrode and defined by the sealing ring.

The elastic diaphragm permits the electrode plate to swivel and to move axially in relation to the sealing ring. Unfortunately, it has been found 25 that because of this freedom of movement the electrode tends to fall away, unless very deep vacuum-pressures are used, i.e. pressures which leave pronounced suction marks. Moreover, there is no guarantee that the electrode pressure will remain 30 constant, and hence the electrical function of the electrode is dependent upon the patient lying quite still. Very small variations are sufficient to produce changes in the contact resistance, such as to cause the base line against which the ECG-variable is re-35 produced on a writer or like recording instrument to become unsteady and variable. Consequently, this method of attaching electrodes to a patient by vacuum through the agency of centrally located suction means, a method which is both practical 40 and advantageous in theory when using many electrodes, has not found wide use in practice.

An object of the present invention is to provide an electrode plate for an ECG type of electrode, to enable the electrode to remain firmly seated, in order better to fulfil its intended purpose. Such an electrode should remain firmly attached to a patient even though the patient may move during the examination; it should avoid the occurrence of base-line variations due to changes in surface-contact pressure; and it should enable fuction tests to be made on the heart of a patient during movement of the patient, something which from a diagnostic aspect is highly desirable, but which is so difficult to carry out when using conventional techniques as to make it impossible to include such a feature in general routine procedures.

An electrode which is held in position by means of suction forces and which has a surrounding sealing ring which is relatively rigidly connected to 60 a centrally located electrode plate, is known from US Patent Specification No. 4 248 243. With this electrode, however, the suction forces cannot be applied through a tube from a central vacuum source, since this electrode design lacks the self-65 closing valve of the Austrian patent, which valve

cannot be combined with the rigid electrode-structure. Instead, this known electrode is supplied with pressurezed air, which drives an ejector-suction device incorporated in the electrode itself. This causes the electrode to be highly disturbing, especially to a patient undergoing an examination, since it emits a high pitched whining noise when seated on the body of the patient. In addition hereto, everything that enters the ejector pipe of the suction device is blown therethrough into the 75 room, for example aerosols containing electrodepaste applied to the electrode, and non-sterile body fluid (from transpiration), and hence when using this electrode there is obtained both sound and other apparent sanitary inconveniences. Be-80 cause of its structural design, such an electrode cannot be sterilized, and neither can it be used in the same manner as a disposable electrode. In addition, the air which drives the ejector must be at a relatively high pressure, approximately 0.6 kg/cm2, which results in sealing problems and requires the use of pressure hoses.

At present there are used mainly two types of electrodes. Firstly, there is used the disposabletype electrode, which is attached with the aid of an adhesive (such as glue, or adhesive tape) or with the aid of rubber bands. Secondly there is used the multi-use electrode which is held in position by a locally generated vacuum force. One well known vacuum principle employs the compression and subsequent expansion of rubber balls. Unfortunately, due to insufficient reservoir sizes, these balls loosen in the event of even very slight leaks, which leads to serious problems when wishing to work, for example, with six electrodes fixed to the patient at the same time, which is normal routine procedure. Consequently, none of these systems is fully satisfactory. These disadvantages are eliminated to a great extent by means of the invention.

100

105

110

115

120

130

Accordingly, the present invention provides an electrode plate for an ECG electrode which is intended to be affixed with the aid of a vacuum applied through a hose, said electrode plate having a front surface comprising an electrode surface coated with a layer of silver chloride; and, on the rear side of the electrode plate, a stem provided with a thickened portion on one end thereof and serving as the male component of a press-stud connector. The electrode using such a plate may partially have the form of a disposable-type electrode or may comprise readily exchangable, sterilizable components. Suitably, the actual electrode plate has the form of a small, throw-away "button", since for electrical reasons the best material from which the electrode surface can be produced is silver with a coating of silver chloride, this material being blackened by light. In this respect, a metal or plastic electrode provided with press-stud attachment means can be given a very thin layer of silver. The sealing ring can also be made of an elastomeric material and the rings changed upon being used once, and collected, washed and sterilized for re-use, unless wishing to design the rings for one-time use only.

The invention will now be described with refer-

ence to an exemplifying embodiment thereof, illustrated in the accompanying drawing in which:-

Figure 1 is an exploded view of an electrode which comprises three parts;

Figure 2 is a sectional view of the electrode in an inoperative position, with the vacuum valve closed; and

Figure 3 is a view of the electrode when affixed to a patient.

The various components of the illustrated embodiment are best seen from Figure 1. An electrode plate 1, which may be made of metal or of a plastics material having a metal surface 4, is provided with protruding portions to afford good con-15 tact with the skin, even in the presence of bodyhair. Located on the rear side of the plate is a stem 5, which forms the male component of a pressstud connector. The stem 5 is intended to be pushed into a press-stud female part 6 located in a 20 backpiece 3, penetrating a hole 18 in an intermediate plate or insert 2 which incorporates, inter alia, a sealing ring 9. As will be understood, the press-

jeans. The backpiece 3 may comprise an electri-25 cally non-conductive plastics material, optionally provided with a metallic screening means (not shown). Connected to the back-piece is a vacuum hose or pipe 8, through which a screened conductor 7 is drawn to the metallic press-stud connector

stud connector is of a conventional kind used with

30 6. Thus, when the connector parts 5, 6 are pressed together, the electrode plate is firmly attached to the backpiece 3 and is connected through the electrical conductor 7 to a conventional ECG machine. The vacuum hose is connected to a cavity in the

35 backpiece 3 and a plurality of holes 20 is located around female part 6 of the connector.

Figure 2 illustrates the electrode components of Figure 1 in their assembled state. For the sake of clarity, only Figure 1 has been provided with com-40 ponent-identifying references. However, the components illustrated in the remaining Figures can be readily identified, by simple comparison with Figure 1. The components 1 and 2 of the illustrated embodiment are rotationally symmetrical, thereby 45 facilitating their manufacture. Such symmetry is not absolutely necessary, however.

The insert 2, which is preferably made of silicone rubber, is provide with a relatively rigidly formed ring portion 9 having extending peripherally ther-50 earound a sealing lip 13, which seals against the skin in the in-use or operative position. The mode of the electrode in the inoperative state thereof will be described first, with reference to Figure 2.

It will be seen that the relatively flat centre part 55 of the insert, exhibiting hole 18, will lie against the sealing lip 15 located on the backpiece 3. The upper side of this centre part, as seen in Figure 1, communicates with the lower side thereof through circumferentially located holes 11. Located on this 60 lower side of the centre part is a further sealing lip 14. The lip 14 abuts the rear face of the electrode plate 1, and both the lip 14 and the lip 15 seal-off a cavity to which a vacuum is applied and which is defined by said centre part and the electrode plate, 65 and hence a certain amount of deflection is ob-

tained in said centre part of the insert 2. This contributes towards resilient abutment of a flange 17, located on the insert 2, with a further lip 16 on the backpiece 3. Thus, in the configuration illustrated in Figure 2, apart from insignificant leakages, only the aforementioned cavity behind the electrode plate 1 will be placed under a vacuum.

When a vacuum is applied to the electrode assembly, shown in Figure 2 and the electrode is placed on the skin of a patient (optionally after applying an electrode paste, which can, however, be omitted), the following happenings occur. When the circumferentially extending lip 13 is pressed against the skin, the force applied herewith will act upon the flange 17, via the relatively inflexible ring 9, therewith to resiliently deform the flange, whereupon the centre part of the insert 2 is deformed and the lip 14 eases away from the rear side of the electrode plate 1. The space or cavity between the skin and the electrode plate 1 is placed in communication with the vacuum source, and since the insert 2 is provided with holes 12 all spaces or electrode-cavities will be placed inder vacuum, the sealing lips 13 and 16 thereby sealing between the backpiece 3 and the skin. The configuration illustrated in Figure 3 is then reached.

It will be clear from Figure 3 that the backpiece 3 and the ring 9 now function as an interlocking composite assembly. Although the ring 9 is urged outwardly, away from the backpiece 3 by an elastic deformation force acting through the flange 17, this force is quite insignificant in comparison with the pneumatic forces. The vacuum used need not reach more than 0.1 kg/cm2. The air pressure then exerts against the skin a force which corresponds substantially to the force exerted by the surface embraced by the lip 13. This force is counteracted by the resistance normally offered by the skin, the greater part of which resistance is exerted on the undersurface 4 of the electrode plate 1, thereby to achieve particularly good contact. Due to deformation of the skin, there is also obtained a certain shape-conforming effect, or embedding effect, which prevents the electrode plate from slipping. Electrode-paste and transpiration tend to reduce friction, and hence this embedding of the electrode is necessary in order to hold the electrode firm against the action of break forces and shear forces. In reality, a break force applied via the hose 8 will 115 cause the skin to accompany the movement until deformation is too great and the lip 13 is no longer able to provide a seal, whereupon the electrode will, of course, fall off, and the resilient flange 13 return to the position shown in Figure 2, with the valve seal once again closed.

100

105

120

130

Thus, in order to obtain good functioning, the electrode surface 4, in the position illustrated in Figure 3, must be inwardly drawn relative to the lip 13 on the ring 9. With a lip of diameter 30 mm, the electrode surface is suitably inwardly drawn to a depth of 3-4 mm. (In the Figures, the illustrated electrode assembly is enlarged by a factor of two).

The described embodiment has been found to function extremely well in practice. For example, six electrodes can be affixed to a patient very

quickly, since no taps need be opened and since all that is required is for the electrodes to be simply pressed, one at a time, onto the skin of the patient, the position where each electrode is to be applied 5 suitably being identified by appropriate symbols placed on the rear surface of respective backpieces. It is found that the presence of body hair presents no problems in this respect, and that the electrodes will remain firmly in position, even 10 should the patient jump barefooted onto the floor. Because of the low suction pressure applied, a tenth of an atmosphere is sufficient, the skin of a normal person will not be marked by the suction applied thereto, apart from a faint red ring where 15 the lip 13 has lain, even should the electrodes be left attached for thirty minutes. Subsequent to using the electrode and disconnecting the vacuum source, all that need be done is to strip off the electrode plate 1 via the press-stud connector, 20 wherewith the elastomeric insert 2 will follow suit, and to place new, or sterilized, components on the backpiece 3 whereupon the electrode is ready for use with a further patient. The components can be readily sterilized, and large numbers can be steri-25 lized at the same time. Thus, electrodes designed in accordance with the invention are extremely practical and hygienic, and permit examinations which have hitherto been troublesome, due to deficiences in electrode functions, to be carried out as 30 a matter of routine. Because of the electrical reliability and stability of the electrode contact, these examinations can be carried out more quickly than was possible hitherto, and previously applied prolonged sampling methods can be shortened. In 35 certain cases, particularly when the electrode is to be used for a longer period of time or for examinations where patients are placed under body stress, it may be suitable to incorporate in the electrode some form of liquid absorbing material, for exam-40 ple blotting paper, this material being placed between the elastomeric component and the backpiece, and being discarded after use.

CLAIMS

45

1. An electrode plate for an ECG electrode which is intended to be affixed with the aid of a vacuum applied through a hose, said electrode plate having a front surface comprising an elec-50 trode surface coated with a layer of silver chloride; and, on the rear side of the electrode plate, a stem provided with a thickened portion on one end thereof and serving as the male component of a press-stud connector.

2. An electrode plate according to Claim 1, wherein the front surface has protruding portions arranged thereon.

3. An electrode plate for an ECG electrode, substantially as hereinbefore described with reference 60 to and as illustrated in the accompanying drawing.