K960721

Paceart Associates LP
510(k) Submission
Paceart Wrist Electrodes
510(K) Summary

JUL 18 1996

(1) Submitter Information:

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(2) Names:

Trade: Paceart Wrist Electrodes
Common Usual Name: Electrocardiograph Wrist Electrodes
Classification Name: Electrode, Electrocardiograph

(3) Classification, Panel

Class II, 74DRX

(4) Predicate Device:

Medtronic 9427 Wrist Electrode

(5) Description

Paceart Wrist Electrodes are metallic electrodes with elastic wristbands intended for electrocardiographic monitoring. Physically the device consists of a flat metallic electrode fastened to a familiar metallic expansion band of the type commonly used with wrist watches. Ordinarily, the patient would have one electrode and band on each wrist. Each electrode has attached to it a single cable, attached to a connector with an oversized pin. The cable is used to provide the connection to the monitor. No gel or other skin preparation is indicated, and in general is not necessary: the patient slips on the bracelet so that the electrode is on the inside of the wrist, and connects the cable connector to a jack on the monitor. The plug is of sufficiently large diameter so that it will not fit into a power outlet. The wrist electrode is used for home telephonic monitoring purposes, and in general will be in contact with the skin for a maximum of five minutes; it is not intended for use as a general-purpose electrocardiographic electrode or for long-term monitoring. The major patient population who is likely to use such an electrode is elderly (for example, pacemaker patients).

(6) Intended Use

Paceart Wrist Electrodes are intended to be used for home monitoring of pacemaker patients via telephone monitoring systems.

(7a) Predicate Devices

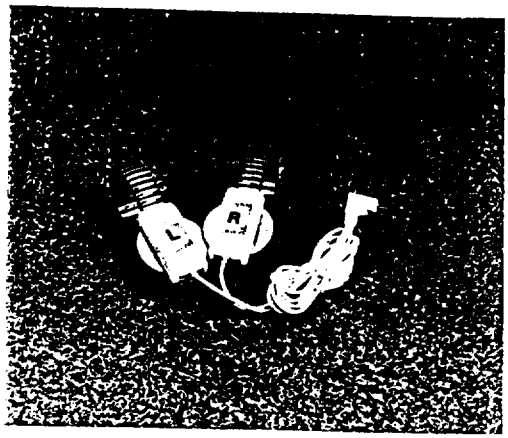
The predicate device for the Paceart Wrist Electrode is the Medtronic 9427 Wrist Electrode

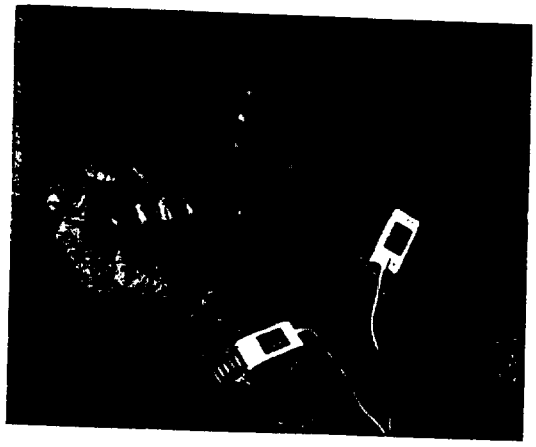
(7b) Testing

The Paceart Wrist Electrode has been compared in tests to the predicate device with respect to noise and offset voltage. The values for the two devices are equivalent. Test reports show that the Paceart Electrode and strap are manufactured from a biologically-compatible stainless steel, Type 304.

These tests all show that the Paceart Wrist Electrode is safe and effective for its intended use.

Photograph
Paceart Wrist Electrode





Paceart Associates LP
510(k) Submission
Paceart Wrist Electrodes
Overview

December 4, 1995

I. Introduction and Intended Use

Paceart Wrist Electrodes are metallic electrodes with elastic wristbands intended for electrocardiographic monitoring. Physically the device consists of a flat metallic electrode fastened to a familiar metallic expansion band of the type commonly used with wrist watches. Ordinarily, the patient would have one electrode and band on each wrist. Each electrode has attached to it a single cable attached to a connector with an oversized pin. The cable is used to provide the connection to the monitor. No gel or other skin preparation is indicated, and in general is not necessary: the patient slips on the bracelet so that the electrode is on the inside of the wrist, and connects the cable to a jack on the monitor by menas of the connector. The plug is of sufficiently large diameter so that it will not fit into a power outlet. The wrist electrode is used for home telephonic monitoring purposes, and in general will be in contact with the skin for a maximum of five minutes; it is not intended for use as a general-purpose electrocardiographic electrode or for long-term monitoring. Since the major patient population who is likely to use such an electrode is quite elderly (for example, pacemaker patients), it is important that the electrode can be easily attached with a minimum of adjustment and preparation.

II. Construction

The device is shown in Figure 1, which shows both the electrode plate and the strap. The electrode material is Type 304 stainless steel, which is an accepted material for implants, a far more stringent application. The materials section has a certificate from the manufacturer showing the composition of this steel. The watch band is a commercial watch band which has been in commercial distribution in the United States for this purpose for some time, with no reported cases of any skin irritations. The cables are shielded, and the shield is connected to a segment of the connector.

One end of each cable (one from each electrode) is permanently attached to one of the electrodes, and cannot be removed by the user. The other ends are permanently

connected to a small jack with a pin which is 3.5 mm in diameter, which is too large to fit into a power outlet. The connections are shown in Figure 2, and the jack is shown schematically in Figure 3.

The jack is specifically made to mate with the Paceart Cardiophone, a trans-telephonic ECG transmitter. However, the electrodes can be used with any other transmitter with a compatible socket. Figure 4 shows more detail of the construction of the electrode.

III. Predicate Device

The predicate device for the Paceart wrist electrode is the Medtronic 9427 wrist electrode, which has the same intended use and virtually the same construction. The characteristics of the two electrodes are compared in the appropriate section of this submission.

IV. Biocompatibility

The only metal in contact with the patient's skin is Type 304 Stainless Steel (the material of both the bracelet and the electrode). Type 304 stainless steel is generally considered to be biologically inert and, in fact, is used for commercial metal watchbands. Since the electrode itself is worn for only short periods of time and is considered inert, there is no risk of biological reaction. Metals are not covered by the tri-partite agreement.

No plastic materials are in contact with the patient.

V. Bench Tests

No AAMI standard exists for this type of electrodes. Therefore, the electrodes have been tested for d-c offset and internal noise, according to AAMI standard EC12-1991, Paragraph 4.2.2.3, and AAMI standard EC12-1991, Paragraph 4.2.2.2. The tests were also run on the predicate device, and the results for the two devices are compared. Results and protocols are in the bench test section.

Since the electrodes are in general used without gel, the offset voltages were measured both with gel (as specified by the standard) and without gel. The Paceart electrodes had a lower offset voltage without gel than did the Medtronic electrodes.

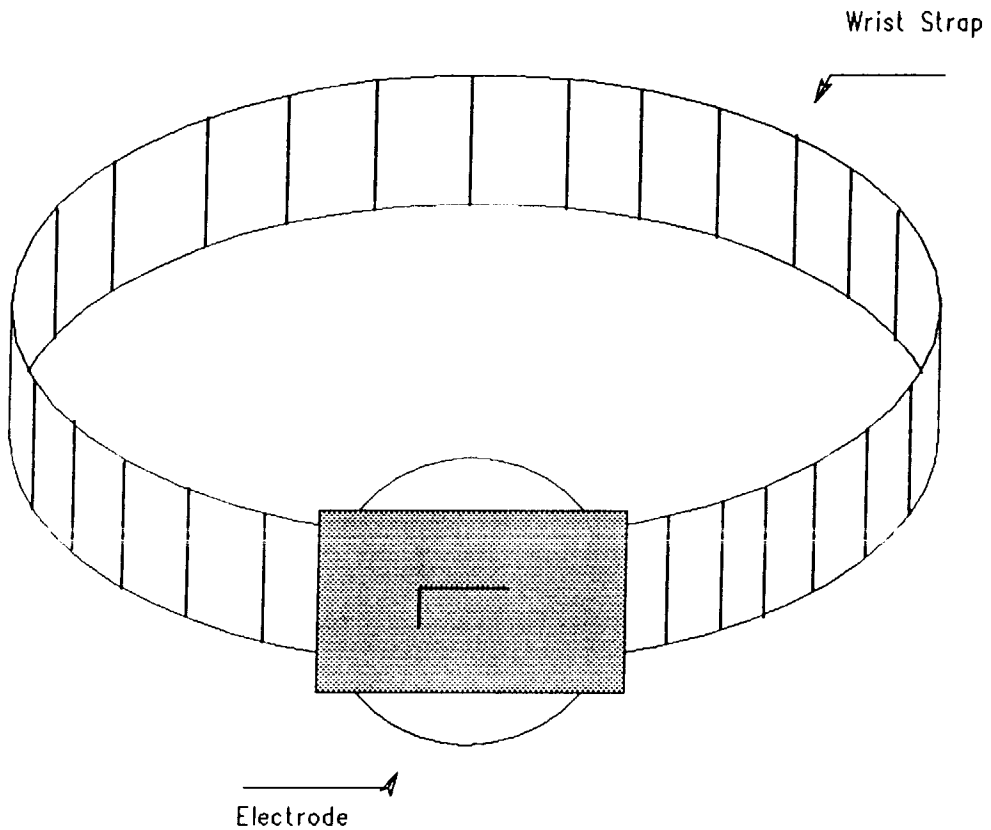
For all tests, both devices had comparable results, and both are better than the AAMI requirements for reusable electrodes.

VI. Clinical Comparison

The Paceart and Medtronic electrodes were compared with a human subject, who wore both sets of electrodes simultaneously, and recorded an ECG using both electrodes at the same time. No gel was used in these tests. The results, shown in the Clinical Section, are virtually identical.

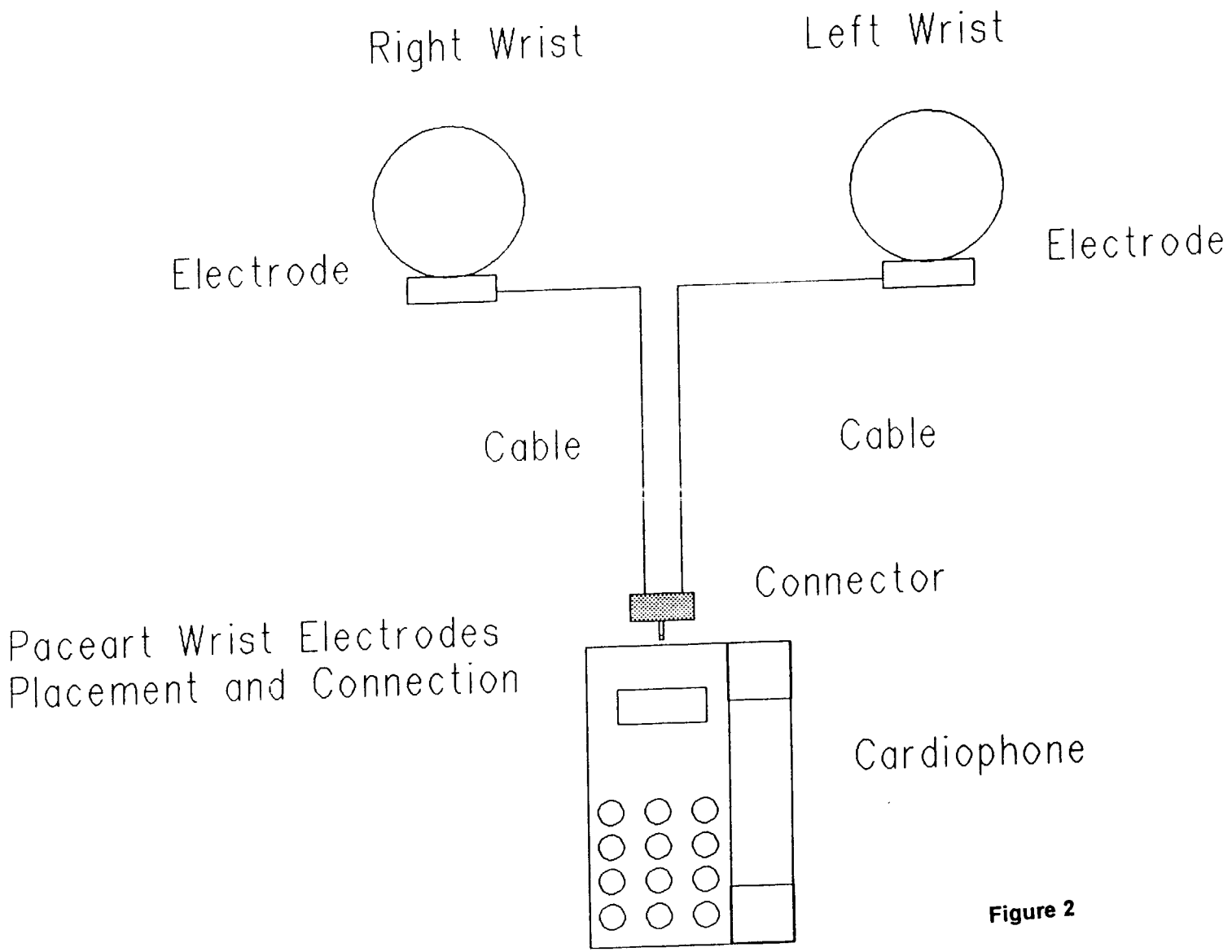
Figures

1. Electrode plate and strap (drawing)
2. Connections
3. Drawing of connecting jack
4. Detail of electrode construction



Paceart Wrist Electrode
Perspective View

Figure 1



Paceart Wrist Electrodes
Placement and Connection

Figure 2

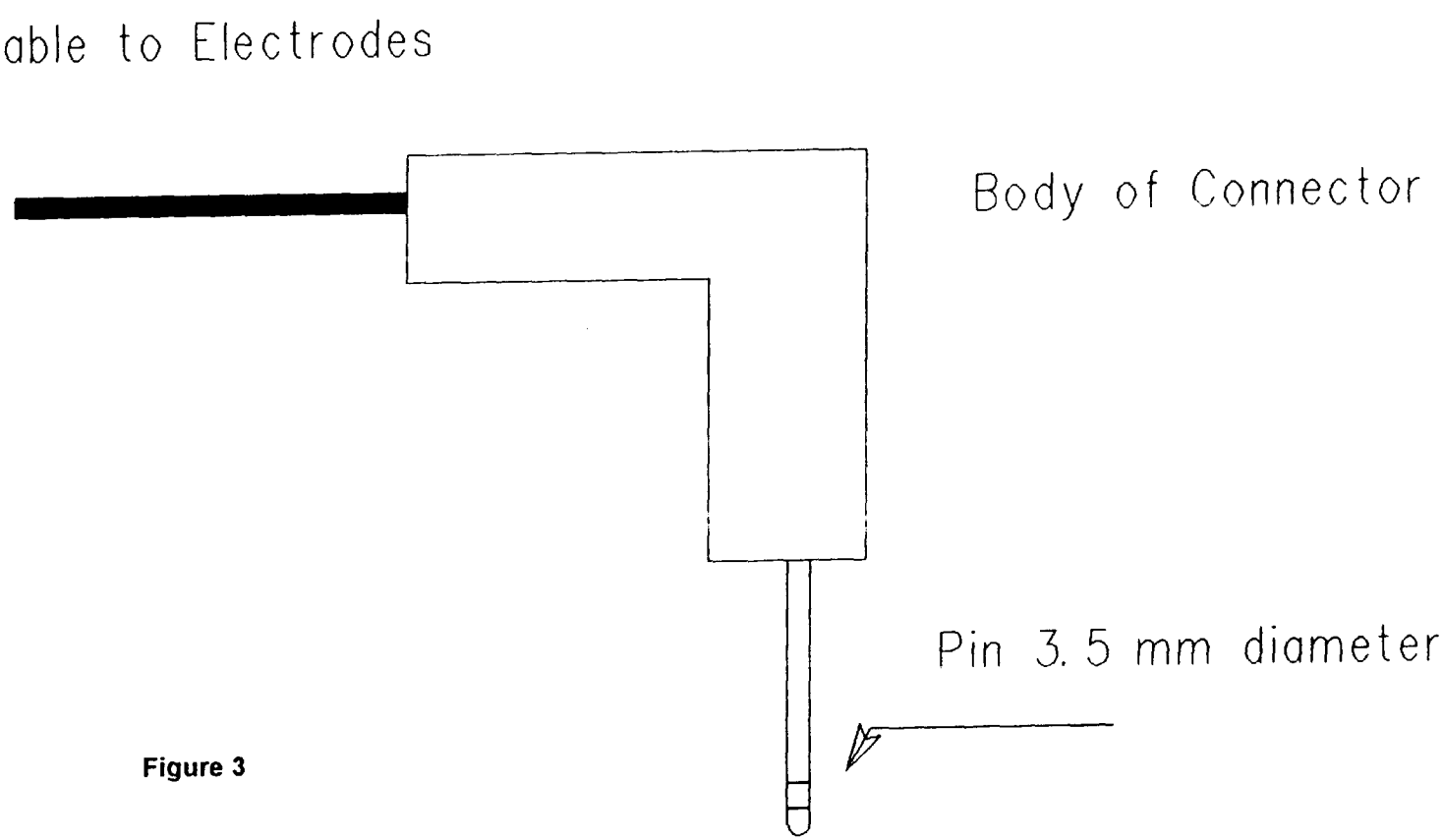


Figure 3

Paceart Wrist Electrode
Connector
Schematic Drawing

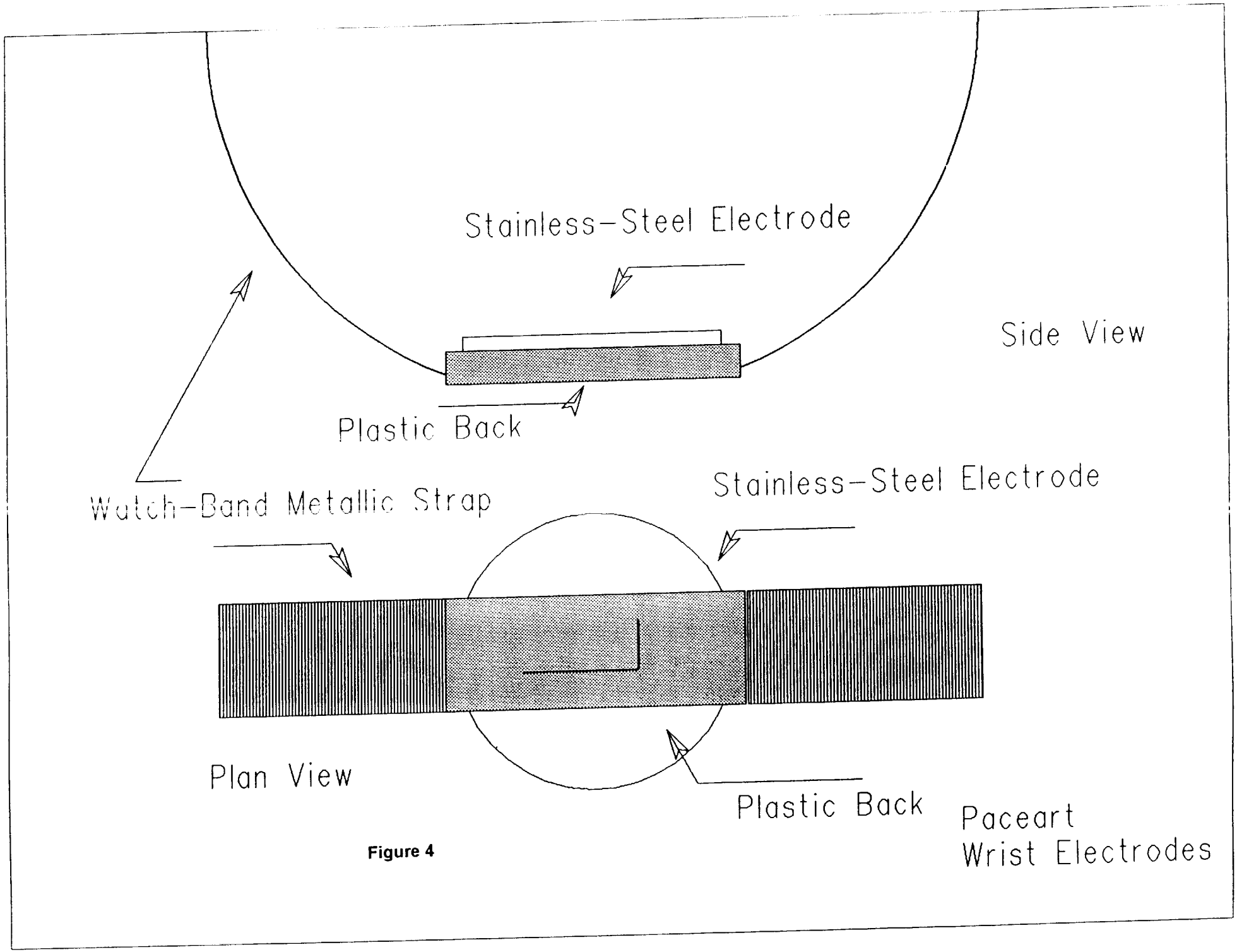

Stainless-Steel Electrode
Side View
Plastic Back
Watch-Band Metallic Strap
Stainless-Steel Electrode
Plan View
Plastic Back
Paceart
Wrist Electrodes

Figure 4