DESIGN AND DEVELOPMENT OF MEDICAL ELECTRONIC INSTRUMENTATION

A Practical Perspective of the Design, Construction, and Test of Medical Devices

DAVID PRUTCHI
MICHAEL NORRIS

A JOHN WILEY & SONS, INC., PUBLICATION

DESIGN AND DEVELOPMENT OF MEDICAL ELECTRONIC INSTRUMENTATION

DESIGN AND DEVELOPMENT OF MEDICAL ELECTRONIC INSTRUMENTATION

A Practical Perspective of the Design, Construction, and Test of Medical Devices

DAVID PRUTCHI
MICHAEL NORRIS

A JOHN WILEY & SONS, INC., PUBLICATION

Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
Published simultaneously in Canada.

Library of Congress Cataloging-in-Publication Data:

Prutchi, David.
Design and development of medical electronic instrumentation: a practical perspective of the design, construction, and test of material devices / David Prutchi, Michael Norris.
p. cm.
Includes bibliographical references and index.
ISBN 0-471-67623-3 (cloth)
1. Medical instruments and apparatus–Design and construction. I. Norris, Michael. II. Title.

R856.P78 2004
681'.761–dc22

2004040853

Printed in the United States of America

10 9 8 7 6 5 4 3 2 1

In memory of Prof. Mircea Arcan,
who was a caring teacher, a true friend,
and a most compassionate human being.
—David

CONTENTS

PREFACE

The medical devices industry is booming. Growth in the industry has not stopped despite globally fluctuating economies. The main reason for this success is probably the self-sustaining nature of health care. In essence, the same technology that makes it possible for people to live longer engenders the need for more health-care technologies to enhance the quality of an extended lifetime. It comes as no surprise, then, that the demand for trained medical-device designers has increased tremendously over the past few years. Unfortunately, college courses and textbooks most often provide only a cursory view of the technology behind medical instrumentation. This book supplements the existing literature by providing background and examples of how medical instrumentation is actually designed and tested. Rather than delve into deep theoretical considerations, the book will walk you through the various practical aspects of implementing medical devices.

The projects presented in the book are truly unique. College-level books in the field of biomedical instrumentation present block-diagram views of equipment, and high-level hobby books restrict their scope to science-fair projects. In contrast, this book will help you discover the challenge and secrets of building practical electronic medical devices, giving you basic, tested blocks for the design and development of new instrumentation. The projects range from simple biopotential amplifiers all the way to a computer-controlled defibrillator. The circuits actually work, and the schematics are completely readable. The project descriptions are targeted to an audience that has an understanding of circuit design as well as experience in electronic prototype construction. You will understand all of the math if you are an electrical engineer who still remembers Laplace transforms, electromagnetic fields, and programming. However, the tested modular circuits and software are easy to combine into practical instrumentation even if you look at them as "black boxes" without digging into their theoretical basis. We will also assume that you have basic knowledge of physiology, especially how electrically excitable cells work, as well as how the aggregate activities of many excitable cells result in the various biopotential signals that can be detected from the body. For a primer (or a refresher), we recommend reading Chapters 6 and 7 of *Intermediate Physics for Medicine and Biology*, 3rd ed., by Russell K. Hobbie (1997).

Whether you are a student, hobbyist, or practicing engineer, this book will show you how easy it is to get involved in the booming biomedical industry by building sophisticated instruments at a small fraction of the comparable commercial cost.

The book addresses the practical aspects of amplifying, processing, simulating, and evoking these biopotentials. In addition, in two chapters we address the issue of safety in the development of electronic medical devices, bypassing the difficult math and providing lots of insider advice.

In Chapter 1 we present the development of amplifiers designed specifically for the detection of biopotential signals. A refresher on op-amp-based amplifiers is presented in the context of the amplification of biopotentials. Projects for this chapter include chloriding silver electrodes, high-impedance electrode buffer array, pasteless bioelectrode, single-ended electrocardiographic (ECG) amplifier array, body potential driver, differential biopotential amplifier, instrumentation-amplifier biopotential amplifier, and switched-capacitor surface array electromyographic amplifier.

In Chapter 2 we look at the frequency content of various biopotential signals and discuss the need for filtering and the basics of selecting and designing *RC* filters, active filters, notch filters, and specialized filters for biopotential signals. Projects include a dc-coupled biopotential amplifier with automatic offset cancellation, biopotential amplifier with dc rejection, ac-coupled biopotential amplifier front end, bootstrapped ac-coupled biopotential amplifier, biopotential amplifier with selectable *RC* bandpass filters, state-variable filter with tunable cutoff frequency, twin-T notch filter, gyrator notch filter, universal harmonic eliminator notch comb filter, basic switched-capacitor filters, slew-rate limiter, ECG amplifier with pacemaker spike detection, "scratch and rumble" filter for ECG, and an intracardiac electrogram evoked-potential amplifier.

In Chapter 3 we introduce safety considerations in the design of medical device prototypes. We include a survey of applicable standards and a discussion on mitigating the dangers of electrical shock. We also look at the way in which equipment should be tested for compliance with safety standards. Projects include the design of an isolated biopotential amplifier, transformer-coupled analog isolator module, carrier-based optically coupled analog isolator, linear optically coupled analog isolator with compensation, isolated eight-channel 12-bit analog-to-digital converter, isolated analog-signal multiplexer, ground bond integrity tester, microammeter for safety testing, and basic high-potential tester.

In Chapter 4 we discuss international regulations regarding electromagnetic compatibility and medical devices. This includes mechanisms of emission of and immunity against radiated and conducted electromagnetic disturbances as well as design practices for electromagnetic compatibility. Projects include a radio-frequency spectrum analyzer, near-field H-field and E-field probes, comb generator, conducted emissions probe, line impedance stabilization network, electrostatic discharge simulators, conducted-disturbance generator, magnetic field generator, and wideband transmitter for susceptibility testing.

In Chapter 5 we present the new breed of "smart" sensors that can be used to detect physiological signals with minimal design effort. We discuss analog-to-digital conversion of physiological signals as well as methods for high-resolution spectral analysis. Projects include a universal sensor interface, sensor signal conditioners, using the PC sound card as a data acquisition card, voltage-controlled oscillator for dc-correct signal acquisition through a sound card, as well as fast Fourier transform and high-resolution spectral estimation software.

In Chapter 6 we discuss the need for artificial signal sources in medical equipment design and testing. The chapter covers the basics of digital signal synthesis, arbitrary signal generation, and volume conductor experiments. Projects include a general-purpose signal generator, direct-digital-synthesis sine generator, two-channel digital arbitrary waveform generator, multichannel analog arbitrary signal source, cardiac simulator for pacemaker testing, and how to perform volume-conductor experiments with a voltage-to-current converter and physical models of the body.

In Chapter 7 we look at the principles and clinical applications of electrical stimulation of excitable tissues. Projects include the design of stimulation circuits for implantable

pulse generators, fabrication of implantable stimulation electrodes, external neuromuscular stimulator, TENS device for pain relief, and transcutaneous/transcranial pulsed-magnetic neural stimulator.

In Chapter 8 we discuss the principles of cardiac pacing and defibrillation, providing a basic review of the electrophysiology of the heart, especially its conduction deficiencies and arrhythmias. Projects include a demonstration implantable pacemaker, external cardiac pacemaker, impedance plethysmograph, intracardiac impedance sensor, external defibrillator, intracardiac defibrillation shock box, and cardiac fibrillator.

The Epilogue is an engineer's perspective on bringing a medical device to market. The regulatory path, Food and Drug Administration (FDA) classification of medical devices, and process of submitting applications to the FDA are discussed and we look at the value of patents and how to recruit venture capital.

Finally, in Appendix A we provide addresses, Web sites, telephone numbers, and fax numbers for suppliers of components used in the projects described in the book. The contents of the book's ftp site, which contains software and information used for many of these projects, is given in Appendix B.

DAVID PRUTCHI
MICHAEL NORRIS

DISCLAIMER

The projects in this book are presented solely as examples of engineering building blocks used in the design of experimental electromedical devices. The construction of any and all experimental systems must be supervised by an engineer experienced and skilled with respect to such subject matter and materials, who will assume full responsibility for the safe and ethical use of such systems.

The authors do not suggest that the circuits and software presented herein can or should be used by the reader or anyone else to acquire or process signals from, or stimulate the living tissues of, human subjects or experimental animals. Neither do the authors suggest that they can or should be used in place of or as an adjunct to professional medical treatment or advice. Sole responsibility for the use of these circuits and/or software or of systems incorporating these circuits and/or software lies with the reader, who must apply for any and all approvals and certifications that the law may require for their use. Furthermore, safe operation of these circuits requires the use of isolated power supplies, and connection to external signal acquisition/processing/monitoring equipment should be done only through signal isolators with the proper isolation ratings.

The authors and publisher do not make any representations as to the completeness or accuracy of the information contained herein, and disclaim any liability for damage or injuries, whether caused by or arising from a lack of completeness, inaccuracy of information, misinterpretation of directions, misapplication of circuits and information, or otherwise. **The authors and publisher expressly disclaim any implied warranties of merchantability and of fitness of use for any particular purpose, even if a particular purpose is indicated in the book.**

References to manufacturers' products made in this book do not constitute an endorsement of these products but are included for the purpose of illustration and clarification. It is not the authors' intent that any technical information and interface data presented in this book supersede information provided by individual manufacturers. In the same way, various government and industry standards cited in the book are included solely for the purpose of reference and should not be used as a basis for design or testing.

Since some of the equipment and circuitry described in this book may relate to or be covered by U.S. or other patents, the authors disclaim any liability for the infringement of

such patents by the making, using, or selling of such equipment or circuitry, and suggest that anyone interested in such projects seek proper legal counsel.

Finally, the authors and publisher are not responsible to the reader or third parties for any claim of special or consequential damages, in accordance with the foregoing disclaimer.

ABOUT THE AUTHORS

David Prutchi is Vice President of Engineering at Impulse Dynamics, where he is responsible for the development of implantable devices intended to treat congestive heart failure, obesity, and diabetes. His prior experience includes the development of Sulzer-Intermedics' next-generation cardiac pacemaker, as well as a number of other industrial and academic positions conducting biomedical R&D and developing medical electronic instrumentation. David Prutchi holds a Ph.D. in biomedical engineering from Tel-Aviv University and conducted postdoctoral research at Washington University, where he taught a graduate course in neuroelectric systems. Dr. Prutchi has over 40 technical publications and in excess of 60 patents in the field of active implantable medical devices.

Michael Norris is a Senior Electronics Engineer at Impulse Dynamics, where he has developed many cardiac stimulation devices, cardiac contractility sensors, and physiological signal acquisition systems. His 25 years of experience in electronics include the development of cardiac stimulation prototype devices at Sulzer-Intermedics as well as the design, construction, and deployment of telemetric power monitoring systems at Nabla Inc. in Houston, and instrumentation and controls at General Electric. Michael Norris has authored various technical publications and holds patents related to medical instrumentation.

1

BIOPOTENTIAL AMPLIFIERS

In general, signals resulting from physiological activity have very small amplitudes and must therefore be amplified before their processing and display can be accomplished. The specifications and lists of characteristics of biopotential amplifiers can be as long and confusing as those for any other amplifier. However, for most typical medical applications, the most relevant amplifier characterizing parameters are the seven described below.

1. Gain. The signals resulting from electrophysiological activity usually have amplitudes on the order of a few microvolts to a few millivolts. The voltage of such signals must be amplified to levels suitable for driving display and recording equipment. Thus, most biopotential amplifiers must have gains of 1000 or greater. Most often the gain of an amplifier is measured in decibels (dB). Linear gain can be translated into its decibel form through the use of

$$\text{Gain(dB)} = 20 \log_{10}(\text{linear gain})$$

2. Frequency response. The frequency bandwidth of a biopotential amplifier should be such as to amplify, without attenuation, all frequencies present in the electrophysiological signal of interest. The bandwidth of any amplifier, as shown in Figure 1.1, is the difference between the upper cutoff frequency f_2 and the lower cutoff frequency f_1. The gain at these cutoff frequencies is 0.707 of the gain in the midfrequency plateau. If the percentile gain is normalized to that of the midfrequency gain, the gain at the cutoff frequencies has decreased to 70.7%. The cutoff points are also referred to as the *half-power points*, due to the fact that at 70.7% of the signal the power will be $(0.707)^2 = 0.5$. These are also known as the -3-dB points, since the gain at the cutoff points is lower by 3 dB than the gain in the midfrequency plateau: $-3\,\text{dB} = 20 \log_{10}(0.707)$.

3. Common-mode rejection. The human body is a good conductor and thus will act as an antenna to pick up electromagnetic radiation present in the environment. As shown in Figure 1.2, one common type of electromagnetic radiation is the 50/60-Hz wave and its harmonics coming from the power line and radiated by power cords. In addition, other spectral components are added by fluorescent lighting, electrical machinery, computers,

Design and Development of Medical Electronic Instrumentation By David Prutchi and Michael Norris
ISBN 0-471-67623-3

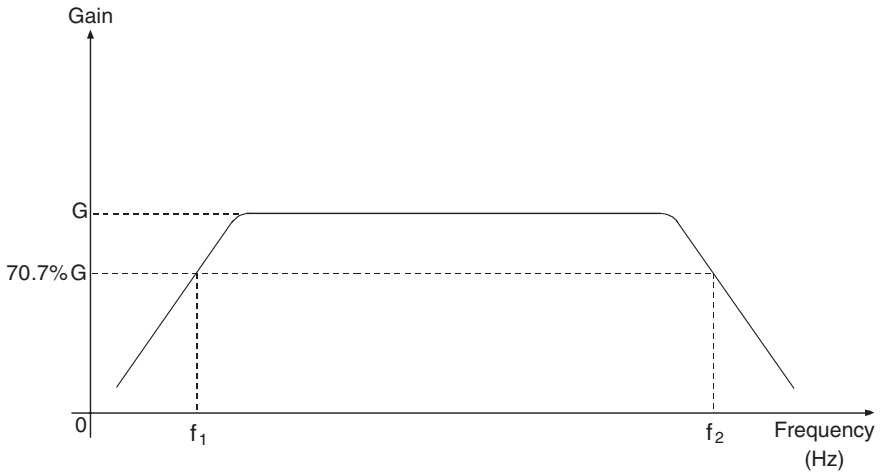

Figure 1.1 Frequency response of a biopotential amplifier.

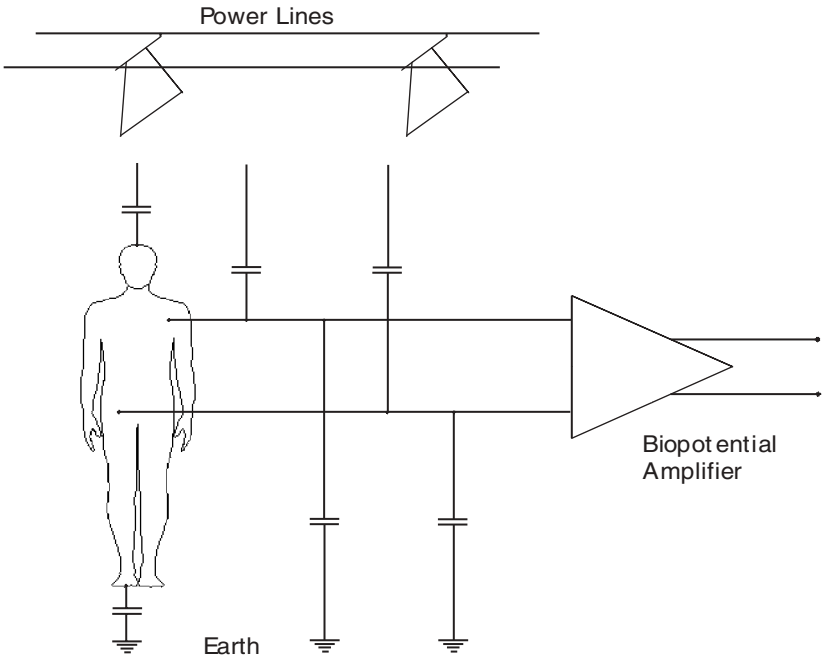

Figure 1.2 Coupling of power line interference to a biopotential recording setup.

and so on. The resulting interference on a single-ended bioelectrode is so large that it often obscures the underlying electrophysiological signals.

The *common-mode rejection ratio* (CMRR) of a biopotential amplifier is measurement of its capability to reject common-mode signals (e.g., power line interference), and it is defined as the ratio between the amplitude of the common-mode signal to the amplitude of an equivalent differential signal (the biopotential signal under investigation) that would produce the same output from the amplifier. *Common-mode rejection* is often expressed in decibels according to the relationship

$$\text{Common-mode rejection (CMR) (dB)} = 20 \log_{10}\text{CMRR}$$

4. Noise and drift. Noise and drift are additional unwanted signals that contaminate a biopotential signal under measurement. Both noise and drift are generated within the amplifier circuitry. The former generally refers to undesirable signals with spectral components above 0.1 Hz, while the latter generally refers to slow changes in the baseline at frequencies below 0.1 Hz.

The noise produced within amplifier circuitry is usually measured either in microvolts peak to peak ($\mu V_{p\text{-}p}$) or microvolts root mean square (RMS) (μV_{RMS}), and applies as if it were a differential input voltage. Drift is usually measured, as noise is measured, in microvolts and again, applies as if it were a differential input voltage. Because of its intrinsic low-frequency character, drift is most often described as peak-to-peak variation of the baseline.

5. Recovery. Certain conditions, such as high offset voltages at the electrodes caused by movement, stimulation currents, defibrillation pulses, and so on, cause transient interruptions of operation in a biopotential amplifier. This is due to saturation of the amplifier caused by high-amplitude input transient signals. The amplifier remains in saturation for a finite period of time and then drifts back to the original baseline. The time required for the return of normal operational conditions of the biopotential amplifier after the end of the saturating stimulus is known as *recovery time*.

6. Input impedance. The input impedance of a biopotential amplifier must be sufficiently high so as not to attenuate considerably the electrophysiological signal under measurement. Figure 1.3*a* presents the general case for the recording of biopotentials. Each electrode–tissue interface has a finite impedance that depends on many factors, such as the type of interface layer (e.g., fat, prepared or unprepared skin), area of electrode surface, or temperature of the electrolyte interface.

In Figure 1.3*b*, the electrode–tissue has been replaced by an equivalent resistance network. This is an oversimplification, especially because the electrode–tissue interface is not merely a resistive impedance but has very important reactive components. A more correct representation of the situation is presented in Figure 1.3*c*, where the final signal recorded as the output of a biopotential amplifier is the result of a series of transformations among the parameters of voltage, impedance, and current at each stage of the signal transfer. As shown in the figure, the electrophysiological activity is a current source that causes current flow i_e in the extracellular fluid and other conductive paths through the tissue. As these extracellular currents act against the small but nonzero resistance of the extracellular fluids R_e, they produce a potential V_e, which in turn induces a small current flow i_{in} in the circuit made up of the reactive impedance of the electrode surface X_{Ce} and the mostly resistive impedance of the amplifier Z_{in}. After amplification in the first stage, the currents from each of the bipolar contacts produce voltage drops across input resistors R_{in} in the summing amplifier, where their difference is computed and amplified to finally produce an output voltage V_{out}.

The skin between the potential source and the electrode can be modeled as a series impedance, split between the outer (epidermis) and the inner (dermis) layers. The outer layer of the epidermis—the stratum corneum—consists primarily of dead, dried-up cells which have a high resistance and capacitance. For a 1-cm^2 area, the impedance of the stratum corneum varies from 200 kΩ at 1 Hz down to 200 Ω at 1 MHz. Mechanical abrasion will reduce skin resistance to between 1 and 10 kΩ at 1 Hz.

7. Electrode polarization. Electrodes are usually made of metal and are in contact with an electrolyte, which may be electrode paste or simply perspiration under the electrode. Ion–electron exchange occurs between the electrode and the electrolyte, which results in voltage known as the *half-cell potential*. The front end of a biopotential amplifier must be able to deal with extremely weak signals in the presence of such dc polarization components. These dc potentials must be considered in the selection of a biopotential amplifier gain, since they can saturate the amplifier, preventing the detection of low-level ac components. International standards regulating the specific performance of biopotential recording systems

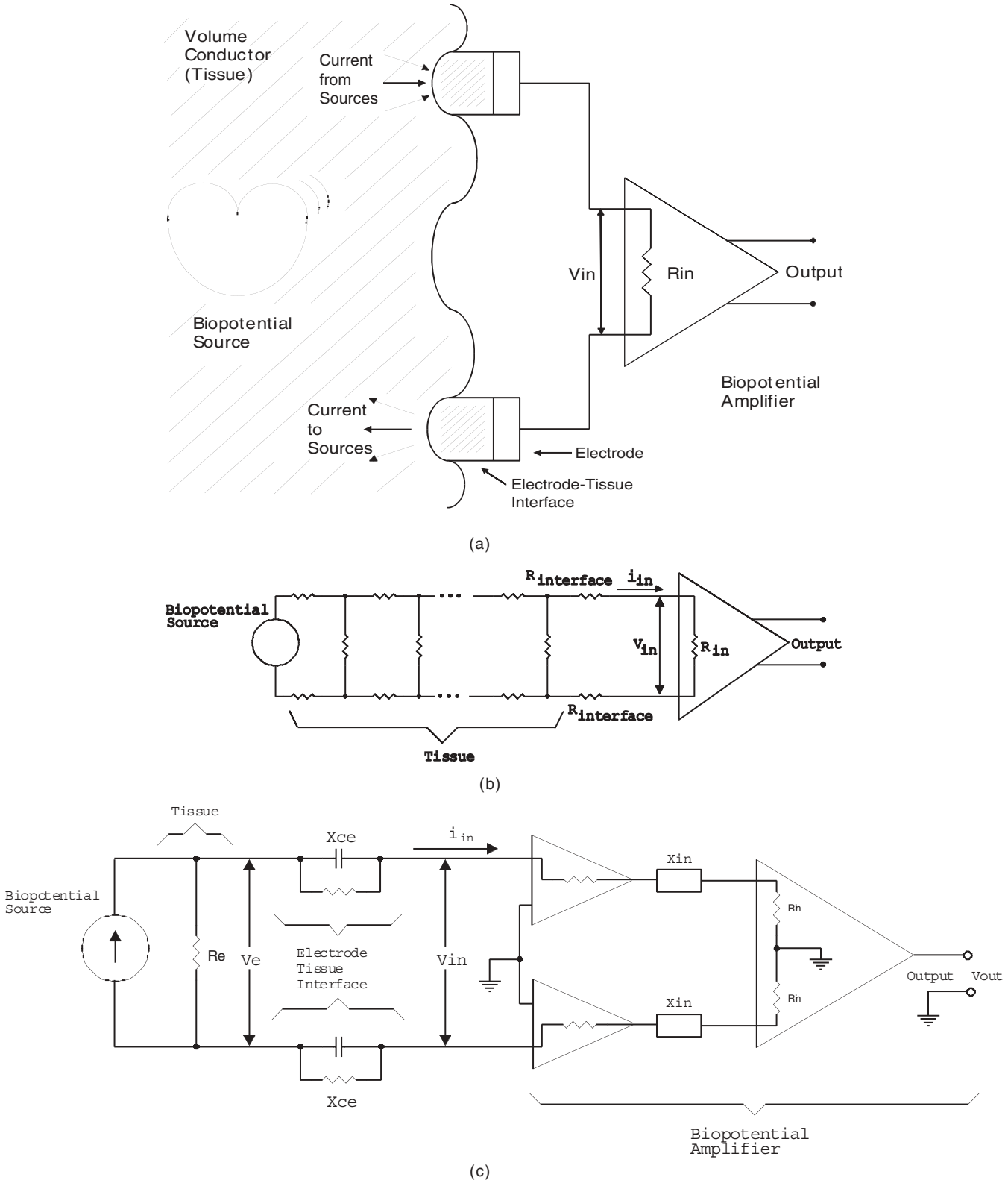

Figure 1.3 (*a*) Simplified view of the recording of biopotentials; (*b*) equivalent circuit; (*c*) generalized equivalent circuit.

usually specify the electrode offsets that are commonly present for the application covered by the standard. For example, the standards issued by the Association for the Advancement of Medical Instrumentation (AAMI) specify that electrocardiography (ECG) amplifiers must tolerate a dc component of up to ± 300 mV resulting from electrode–skin contact.

Commercial ECG electrodes have electrode offsets that are usually low enough, ensuring little danger of exceeding the maximum allowable dc input offset specifications of the standards. However, the design of a biopotential amplifier must consider that there are times when the dc offset may be much larger. For example, neonatal ECG monitoring applications often use sets of stainless-steel needle electrodes, whose offsets are much higher than those of commercial self-adhesive surface ECG electrodes. In addition, many physicians still prefer to use nondisposable suction cup electrodes (which have a rubber squeeze bulb attached to a silver-plated brass hemispherical cup). After the silver plating wears off, these brass cup electrodes can introduce very large offsets.

LOW-POLARIZATION SURFACE ELECTRODES

Silver (Ag) is a good choice for metallic skin-surface electrodes because silver forms a slightly soluble salt, silver chloride (AgCl), which quickly saturates and comes to equilibrium. A cup-shaped electrode provides enough volume to contain an electrolyte, including chlorine ions. In these electrodes, the skin never touches the electrode material directly. Rather, the interface is through an ionic solution.

One simple method to fabricate Ag/AgCl electrodes is to use electrolysis to chloride a silver base electrode (e.g., a small silver disk or silver wire). The silver substrate is immersed in a chlorine-ion-rich solution, and electrolysis is performed using a common 9-V battery connected via a series 10-kΩ potentiometer and a milliammeter. The positive terminal of the battery should be connected to the silver metal, and a plate of platinum or silver should be connected to the negative terminal and used as the opposite electrode in the solution. Our favorite electrolyte is prepared by mixing 1 part distilled water (the supermarket kind is okay), 1/2 part HCl 25%, and $FeCl_3$ at a rate of 0.5 g per milliliter of water.

If you want to make your own electrodes, use refined silver metal (99.9 to 99.99% Ag) to make the base electrode. Before chloriding, degrease and clean the silver using a concentrated aqueous ammonia solution (10 to 25%). Leave the electrodes immersed in the cleaning solution for several hours until all traces of tarnish are gone. Rinse thoroughly with deionized water (supermarket distilled water is okay) and blot-dry with clean filter paper. Don't touch the electrode surface with bare hands after cleaning. Suspend the electrodes in a suitably sized glass container so that they don't touch the sides or bottom. Pour the electrolyte into the container until the electrodes are covered, but be careful not to immerse the solder connections or leads that you will use to hook up to the electrode.

When the silver metal is immersed, the silver oxidation reaction with concomitant silver chloride precipitation occurs and the current jumps to its maximal value. As the thickness of the AgCl layer deposited increases, the reaction rate decreases and the current drops. This process continues, and the current approaches zero. Adjust the potentiometer to get an initial current density of about 2.5 mA/cm^2, making sure that no hydrogen bubbles evolve at the return electrode (large platinum or silver plate). You should remove the electrode from the solution once the current density drops to about 10 μA/cm^2. Coating should take no more than 15 to 20 minutes. Once done, remove the electrodes and rinse them thoroughly but carefully under running (tap) water.

An alternative to the electrolysis method is to immerse the silver electrode in a strong bleach solution. Yet another way of making a Ag/AgCl electrode is to coat by dipping the silver metal in molten silver chloride. To do so, heat AgCl in a small ceramic crucible with a gas flame until it melts to a dark brown liquid, then simply dip the electrode in the molten silver chloride.

Warning! The materials used to form Ag/AgCl electrodes are relatively dangerous. Do not breathe dust or mist and do not get in eyes, on skin, or on clothing. When working with these materials, safety goggles must be worn. Contact lenses are not protective devices. Appropriate eye and face protection must be worn instead of, or in conjunction with, contact lenses. Wear disposable protective clothing to prevent exposure. Protective clothing includes lab coat and apron, flame- and chemical-resistant coveralls, gloves, and boots to prevent skin contact. Follow good hygiene and housekeeping practices when working with these materials. Do not eat, drink, or smoke while working with them. Wash hands before eating, drinking, smoking, or applying cosmetics.

If you don't want to fabricate your own electrodes, you can buy all sorts of very stable Ag/AgCl electrodes from In Vivo Metric. They make them using a very fine grained homogeneous mixture of silver and silver chloride powder, which is then compressed and sintered into various configurations. Alternatively, Ag/AgCl electrodes are cheap enough that you may get a few pregelled disposable electrodes free just by asking at the nurse's station in the emergency department or cardiology service of your local hospital.

Recording gel is available at medical supply stores (also from In Vivo Metric). However, if you really want a home brew, heat some sodium alginate (pure seaweed, commonly used to thicken food) and water with low-sodium salt (e.g., Morton Lite Salt) into a thick soup that when cooled can be applied between the electrodes and skin. Note that there is no guarantee that this concoction will be hypoallergenic! A milder paste can be made by dissolving 0.9 g of pure NaCl in 100 mL of deionized water. Add 2 g of pharmaceutical-grade Karaya gum and agitate in a magnetic stirrer for 2 hours. Add 0.09 g of methyl paraben and 0.045 g of propyl paraben as preservatives and keep in a clean capped container.

SINGLE-ENDED BIOPOTENTIAL AMPLIFIERS

Most biopotential amplifiers are operational-amplifier-based circuits. As a refresher, the voltage present at the output of the operational amplifier is proportional to the differential voltage across its inputs. Thus, the noninverting input produces an in-phase output signal, while the inverting input produces an output signal that is 180° out of phase with the input.

In the circuit of Figure 1.4, an input signal V_{in} is presented through resistor R_{in} to the inverting input of an ideal operational amplifier. Resistor R_f provides feedback from the amplifier's output to its inverting input. The noninverting input is grounded, and due to the fact that in an ideal op-amp the setting conditions at one input will effectively set the same conditions at the other input, point A can be treated as it were also grounded. The power connections have been deleted for the sake of simplicity.

Ideal op-amps have an infinite input impedance, which implies that the input current i_{in} is zero. The inverting input will neither sink nor source any current. According to Kirchhoff's current law, the total current at junction A must sum to zero. Hence,

$$-i_{\text{in}} = i_f$$

But by Ohm's law, the currents are defined by

$$i_{\text{in}} = \frac{V_{\text{in}}}{R_{\text{in}}}$$

and

$$i_f = -\frac{V_{\text{out}}}{R_f}$$

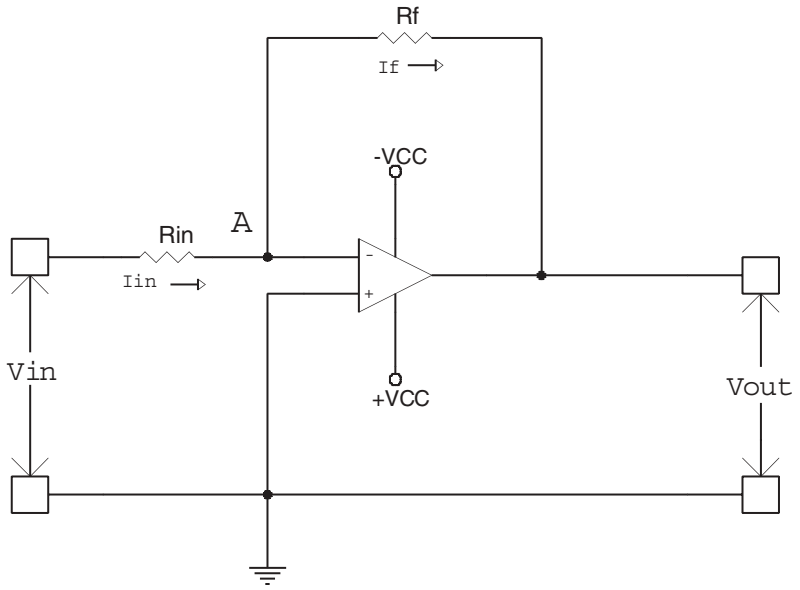

Figure 1.4 Inverting voltage amplifier.

Therefore, by substitution and by solving for V_{out},

$$V_{out} = \frac{R_f V_{in}}{R_{in}}$$

This equation can be rewritten as

$$V_{out} = -GV_{in}$$

where G represents the voltage gain constant R_f/R_{in}.

The circuit presented in Figure 1.5 is a noninverting voltage amplifier, also known as a *noninverting follower*, which can be analyzed in a similar manner. The setting of the noninverting input at input voltage V_{in} will force the same potential at point A. Thus,

$$i_{in} = \frac{V_{in}}{R_{in}}$$

and

$$i_f = \frac{V_{out} - V_{in}}{R_f}$$

But in the noninverting amplifier $i_{in} = i_{out}$, so by replacing and solving for V_{out}, we obtain

$$V_{out} = \left(1 + \frac{R_f}{R_{in}}\right) V_{in}$$

The voltage gain in this case is

$$G = 1 + \frac{R_f}{R_{in}}$$

A special case of this configuration is shown in Figure 1.6. Here $R_f = 0$, and R_{in} is unnecessary, which leads to a resistance ratio $R_f/R_{in} = 0$, which in turn results in unity gain. This configuration, termed a *unity-gain buffer* or *voltage follower*, is often used in biomedical instrumentation to couple a high-impedance signal source, through the (almost) infinite input impedance of the op-amp, to a low-impedance processing circuit connected to the very low impedance output of the op-amp.

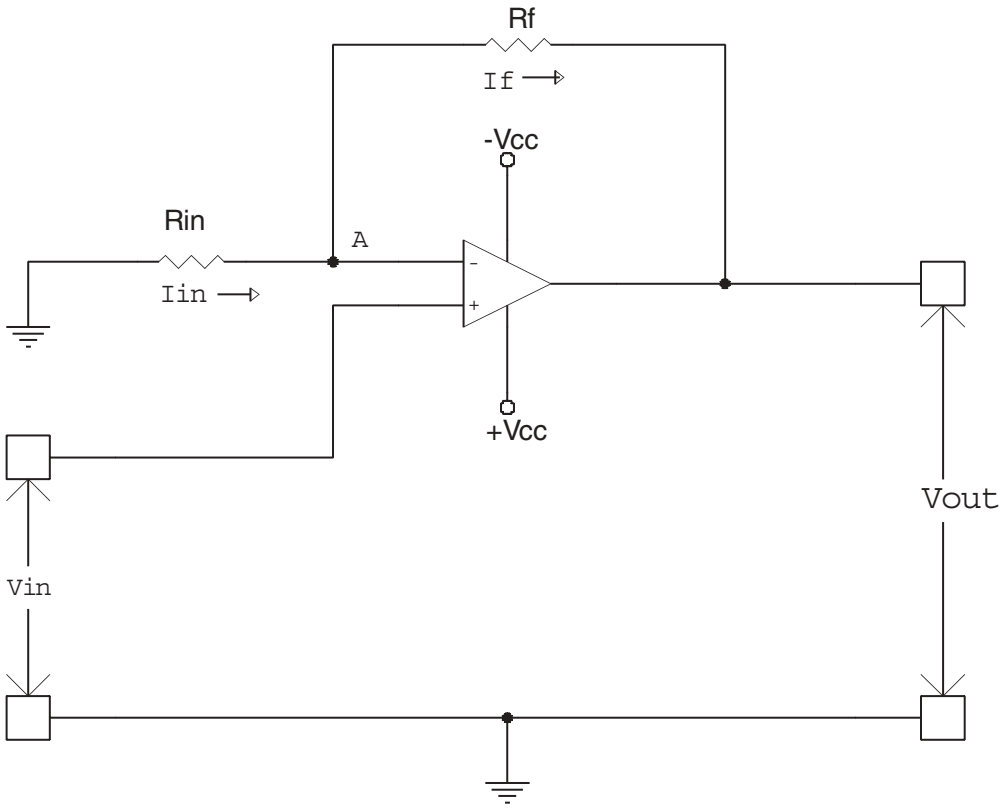

Figure 1.5 Noninverting op-amp voltage amplifier; also known as a noninverting follower.

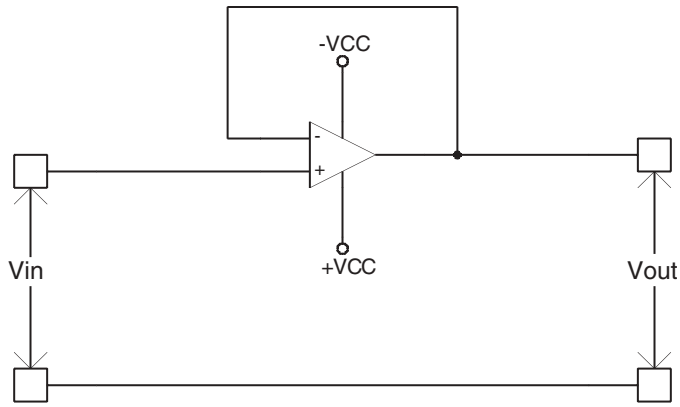

Figure 1.6 A unity-gain buffer is a special case of the noninverting voltage amplifier in which the resistance ratio is $R_f/R_{in} = 0$, which translates into unity gain. This configuration is often used in biomedical instrumentation to buffer a high-impedance signal source.

ULTRAHIGH-IMPEDANCE ELECTRODE BUFFER ARRAYS

A group of ultrahigh-impedance, low-power, low-noise op-amp voltage followers is commonly used as a buffer for signals collected from biopotential electrode arrays. These circuits are usually placed in close proximity to the subject or preparation to avoid contamination and degradation of biopotential signals. The circuit of Figure 1.7 comprises 32 unity-gain

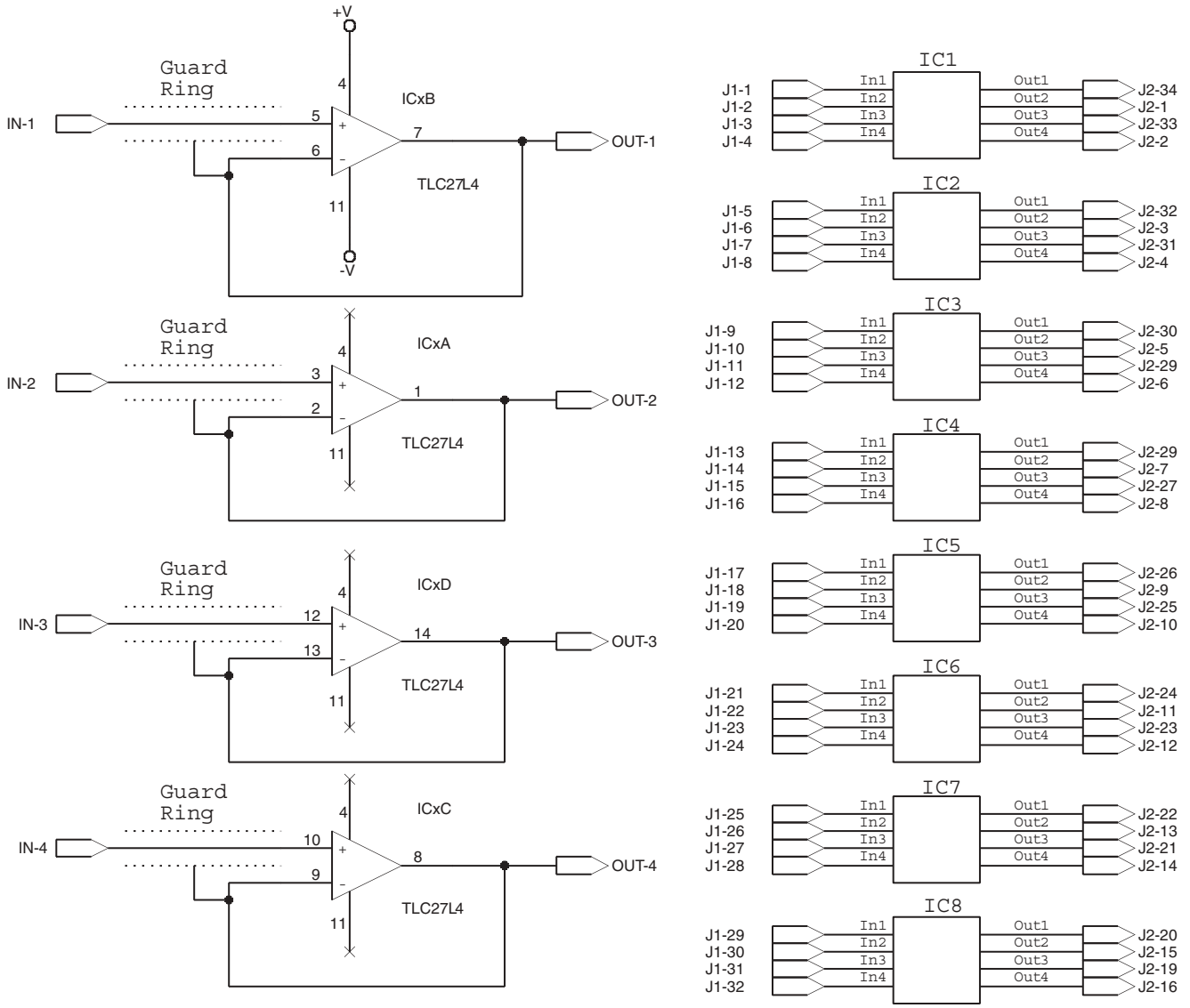

Figure 1.7 CMOS-input unity-gain buffers are often placed in close proximity to high-impedance electrodes to provide impedance conversion, making it possible to transmit the signal over relatively long distances without picking up noise, despite the fact that the contact impedance of the electrodes may range into the thousands of megohms.

buffers, which present an ultrahigh input impedance to an array of up to 32 electrodes. Each buffer in the array is implemented using a LinCMOS[1] precision op-amp operated as a unity-gain voltage follower. An output signal has the same amplitude as that of its corresponding input. The output impedance is very low, however (in the few kilohm range) and can source or sink a maximum of 25 mA. As a result of this impedance transformation, the signal at the buffer's output can be transmitted over long distances without picking up noise, despite the fact that the contact impedance of the electrodes may range into the thousands of megohms. Power for the circuit must be symmetrical ± 3 to ± 9 V dc with real or virtual ground.

In the circuit, input signals at J1 are buffered by eight TLC27L4 precision quad op-amp. The buffered output is available at J2. Despite its apparent simplicity, the circuit must be

[1]LinCMOS is a trademark of Texas Instruments Incorporated.

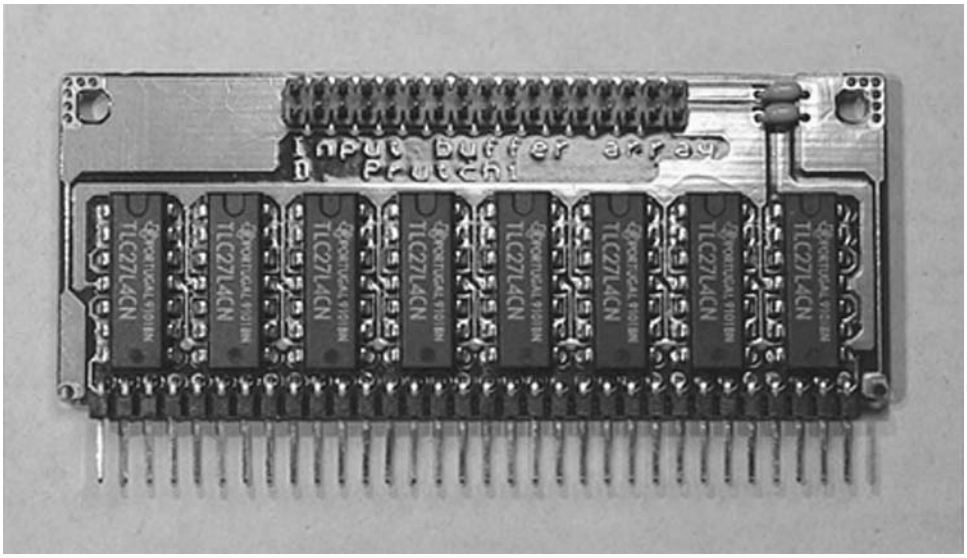

Figure 1.8 Printed circuit board for a high-input-impedance buffer array. The output of each channel is used to drive guard rings which form low-impedance isopotential barriers that shield all input paths from leakage currents.

laid out and constructed with care to take advantage of the op-amp's high input impedance. As shown in the PCB layout of Figure 1.8, the output of each channel is used to drive guard rings that form low-impedance isopotential barriers that shield all input paths from leakage currents.

The selection of op-amps from the TLC27 family has the additional advantage that electrostatic display (ESD) protection circuits that may degrade high input impedance are unnecessary because LinCMOS chips have internal safeguards against high-voltage static charges. Applications requiring ultrahigh input impedances (on the order of $10^{10}\,\Omega$) necessitate additional precautions to minimize stray leakage. These precautions include maintaining all surfaces of the printed circuit board (PCB), connectors, and components free of contaminants, such as smoke particles, dust, and humidity. Residue-free electronic-grade aerosols can be used effectively to dust off particles from surfaces. Humidity must be leached out from the relatively hygroscopic PCB material by drying the circuit board in a low-pressure oven at 40°C for 24 hours and storing in sealed containers with dry silica gel. If even higher input impedances are required, approaching the maximal input impedance of the TLC24L4, you may consider using Teflon[2] PCB material instead of the more common glass–epoxy type.

Typical applications for this circuit include active *medallions*, which are electrode connector blocks mounted in close proximity to the subject or preparation. The low input noise ($68\,\text{nV}/\sqrt{\text{Hz}}$) and high bandwidth (dc—10 kHz) make it suitable for a broad range of applications. For example, 32 standard Ag/AgCl electroencephalography (EEG) electrodes for a brain activity mapper could be connected to such a medallion placed on a headcap.

Figure 1.9 shows another application for the circuit as an active electrode array in electromyography (EMG). Here eight arrays were used to pick up muscle signals from 256 points. Connectors J1 in each of the circuits were made of L-shaped gold-plated pins that are used as electrodes to form an array with a spatial sampling period of 2.54 mm (given by the pitch of a standard connector with 0.1-in. pin center to center). The outputs of the op-amp buffers can then carry signals to the main biopotential signal amplifiers and signal processors

[2]Teflon is a trademark of the DuPont Corporation.

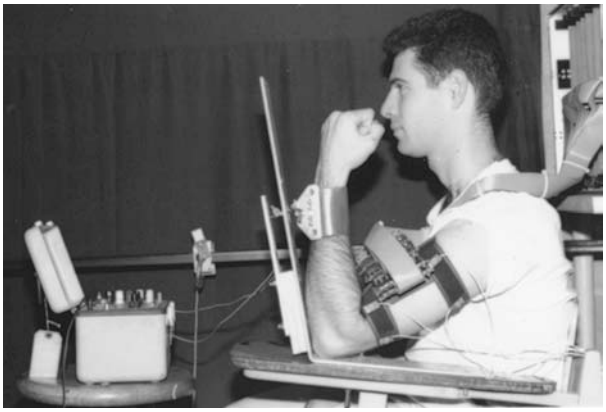

Figure 1.9 Eight high-input-impedance buffer arrays are used to detect muscle signals from 256 points for a high-resolution large-array surface electromyography system. Arrays of gold-plated pins soldered directly to array inputs are used as the electrodes.

using a long flat cable. Power could be supplied either locally, using a single 9-V battery and two 10-kΩ resistors, to create a virtual ground, or directly from a remotely placed symmetrical isolated power supply.

Low-impedance op-amp outputs are compatible with the inputs of most biopotential amplifiers. Wires from J2 can be connected to the inputs of instrumentation just as normal electrodes would. The isolated common post of the biopotential amplifiers should be connected to the ground electrode on the subject or preparation as well as to the ground point of the buffer array.

PASTELESS BIOPOTENTIAL ELECTRODES

Op-amp voltage followers are often used to buffer signals detected from biopotential sources with intrinsically high input impedance. One such application is detecting biopotential signals through capacitive bioelectrodes. One area in which these electrodes are particularly useful is in the measurement and analysis of biopotentials in humans subjected to conditions similar to those existing during flight. Knowledge regarding physiological reactions to flight maneuvers has resulted in the development of devices capable of predicting, detecting, and preventing certain conditions that might endanger the lives of crew members. For example, the detection of gravitationally induced loss of consciousness (loss of consciousness caused by extreme *g*-forces during sharp high-speed flight maneuvers in war planes) may save many pilots and their aircraft by allowing an onboard computer to take over the controls while the aviator regains consciousness [Whinnery et al., 1987]. G_{z+}-induced loss of consciousness (GLOC) detection is achieved through the analysis of various biosignals, the most important of which is the electroencephalogram (EEG).

Another new application is the use of the electrocardiography (ECG) signal to synchronize the inflation and deflation of pressure suits adaptively to gain an increase in the level of gravitational accelerations that an airman is capable of tolerating. Additional applications, such as the use of the processed electromyography (EMG) signal as a measure of muscle fatigue and pain as well as an analysis of eye blinks and eyeball movement through the detection of biopotentials around the eye as a measure of pilot alertness, constitute the promise of added safety in air operations.

One problem in making these techniques practical is that most electrodes used for the detection of bioelectric signals require skin preparation to decrease the electrical impedance

of the skin–electrode interface. This preparation often involves shaving, scrubbing the skin, and applying an electrolyte paste: actions unacceptable as part of routine preflight procedures. In addition, the electrical interface characteristics deteriorate during long-term use of these electrodes as a result of skin reactions and electrolyte drying. Dry or *pasteless electrodes* can be used to get around the constraints of electrolyte–interface electrodes. Pasteless electrodes incorporate a bare or dielectric-coated metal plate, in direct contact with the skin, to form a very high impedance interface. By using an integral high-input-impedance amplifier, it is possible to record a signal through the capacitive or resistive interface.

Figure 1.10 presents the constitutive elements of a capacitive pasteless bioelectrode. In it, a highly dielectric material is used to form a capacitive interface between the skin and a conductive plate electrode. Ideally, this dielectric layer has infinite leakage resistance, but in reality this resistance is finite and decreases as the dielectric deteriorates. Signals presented to the buffer stage result from capacitive coupling of biopotentials to the network formed by series resistor R1 and the input impedance Z_{in} of the buffer amplifier. In addition, circuitry that is often used to protect the buffer stage from ESD further attenuates available signals. Shielding is usually provided in the enclosure of a bioelectrode assembly to protect it from interfering noise. The signal at the output of the buffer amplifier has low impedance and can be relayed to remotely placed processing apparatus without attenuation. External power must be supplied for operation of the active buffer circuitry.

A dielectric substance is used in capacitive biopotential electrodes to form a capacitor between the skin and the recording surface. Thin layers of aluminum anodization, pyre varnish, silicon dioxide, and other dielectrics have been used in these electrodes. For example, 17.5-μm (0.7-mil) film is easily prepared by anodic treatment, resulting in electrode plates that have a dc resistance greater than 1 GΩ and a capacitance of 5000 pF at

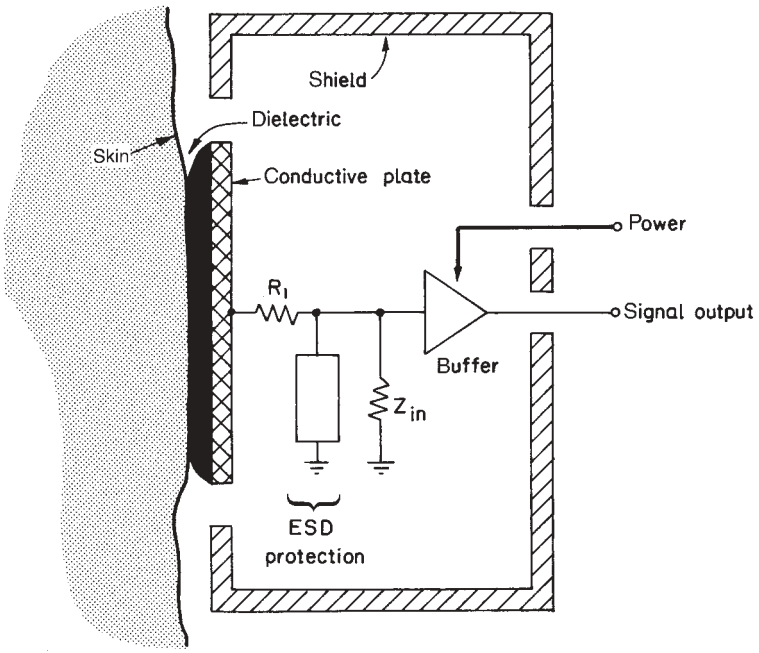

Figure 1.10 Block diagram of a typical capacitive active bioelectrode. A highly dielectric material is used to form a capacitive interface between the skin and a conductive plate electrode. Signals presented to the buffer stage result from capacitive coupling of biopotentials to the network formed by series resistor R1 and the input impedance Z_{in} of the buffer amplifier. (Reprinted from Prutchi and Sagi-Dolev [1993], with permission from the Aerospace Medical Association.)