DESIGN AND DEVELOPMENT OF MEDICAL ELECTRONIC INSTRUMENTATION

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

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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,

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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

presented by the authors for reference purposes only and is not necessarily what Electronic Design & Research places within their "black boxes." No external components (besides power supply and reference signal source) are needed to use these modules. These modules are definitely recommended for applications that can tolerate their size (3.9 in. × 2 in. footprint, 1 in. height) and cost ($221 for the EDR-82534 and $324 for the EDR-82534A in single units).

SWITCHED-CAPACITOR FILTERS

Lately, many designers have opted for switched-capacitor filters as substitutes for continuous-time active filters. Switched-capacitor filters allow sophisticated, accurate, and tunable analog filter circuits to be manufactured without resistors. The advantage of this is that resistors take up considerable room on integrated circuits and that it is next to impossible to maintain a consistent absolute resistance value from manufacturing run to manufacturing run.

In Chapter 1 we showed how a sampling capacitor C_S, which switches continuously between an input voltage and a hold capacitor C_H with a clock period T, acts as a low-pass filter with a −3-dB cutoff frequency defined by the capacitor ratio

$$\frac{C_H}{C_S} = \frac{1}{2\pi f_{-3dB} T}$$

Capacitor ratios are much easier to maintain from batch to batch of an IC than are precise resistor values. In addition, resistor values that would be prohibitive for integration can easily be synthesized through the resistor equivalence of the switched capacitor. Finally, equivalent resistor values can be tuned simply by changing the switching frequency.

Commercial switched-capacitor ICs based on the same principle offer complete or nearly complete high-order filters in small, inexpensive packages. By switching the capacitor at around 100 times the corner frequency, these filters can attain a good approximation of theoretical performance. Switched-capacitor ICs are available as complete filters or as universal building blocks that require few external capacitors or resistors. Driving clocks may be internal or external to the filter itself. Varying clock frequency permits programming filters "on the fly."

If you are not sure which filter transfer function will work best in your application, switched-capacitor filters can help you try out various possibilities without rewiring your circuit. This is because switched-capacitor manufacturers offer filters with the various transfer functions in pin-compatible packages. For example, the Maxim MAX290 family of low-pass filters offers interchangeable chips that implement Bessel, Butterworth, and elliptic-response transfer functions.

Switched-capacitor filters do have disadvantages. For one, since a switched-capacitor filter is a sampling device, it can result in aliasing errors. Frequency components near and above half the sampling frequency must be eliminated to ensure accuracy. In addition, the output of a switched-capacitor filter usually needs to be low-pass filtered with a continuous-time filter to eliminate clocking signals that always manage to feed through.

The use of switched-capacitor filters can present other traps to the designer of biopotential amplifiers. This is because high-speed clock signals can easily couple to the high-impedance inputs and ground lines. Furthermore, the internal amplifiers within switched-capacitor filter ICs can generate noise and harmonic distortion on processed biopotential signals. Regardless of the precautions that one may take in the design, continuous-time active filters end up being at least 20 to 40 dB quieter than their switched-capacitor counterparts.

pulse width selection is accomplished through rotary switches that select a resistor used within a voltage-divider circuit fed from the battery voltage. The output of the resistive divider is measured by one of IC4's analog inputs. Different voltages are mapped by the microcontroller to the various parameter value selections.

Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery (e.g., a Panasonic lithium carbon monofluoride battery). Please note that pacing pulse amplitude and sensing sensitivity vary as a function of battery voltage. Although two regular alkaline batteries in series could be used to power the circuit, the lithium carbon monofluoride chemistry has an almost flat discharge curve which minimizes the shift in the sensing threshold as battery capacity is used.

Almost all commercially available implantable pacemakers designed in the last 20 years use lithium–iodide cells (Li/I_2). These cells are designed to deliver current drains in the microampere range, reliably over long periods of time. They are available from Wilson Greatbatch Technologies, Inc. in a variety of sizes, shapes, and capacities. Lately, implantable-grade lithium carbon monofluoride (Li/CFx) are being used more and more in pacemakers and other implantable devices. The internal impedance of the CFx cell is much lower than that of the Li/I_2 cell throughout its entire life, allowing more flexibility in circuit design and performance. Wilson Greatbatch Technologies, Inc. now has Li/CFx batteries, which feature a titanium case, making it weigh half of a Li/I_2 cell of the same capacity.

Firmware for the VVI Pacemaker

The microcontroller runs algorithms that implement the state machine as well as stimulus routines. Firmware for pacemakers is usually coded in assembly language due to reliability concerns as well as real-time and power consumption issues. For clarity in this example, however, programming was done in C. Despite this, power consumption and real-time performance are reasonable, and use of a high-level language could be used to develop code for an implantable device.

The basic state machine for a VVI pacemaker was shown in Figure 8.6. However, enhancements are required to enable the logic to discriminate true intrinsic cardiac events from interference, such that pacing therapy is inhibited only when true ventricular activity occurs. A possible way of implementing a discrimination mechanism is to use dedicated hardware to prevent interfering signals from triggering a sense event at the microprocessor's input. For example, a retriggerable monostable together with edge-triggered sensing by the microprocessor would be able to cope with noise. However, this implementation requires additional circuitry and does not lend itself to real-time reporting of noise detection. Instead, this pacemaker design incorporates software mechanisms to detect noise and change the device's behavior to prevent noise from inappropriately inhibiting pacing therapy.

International standards that define the minimum requirements for pacemakers establish that devices must consider events detected repeating at more than 10 Hz to be noise. When such a condition is detected, a VVI pacemaker must automatically switch the mode to VOO. The device should remain in this asynchronous mode until normal sensing is resumed. Events detected at a rate below 10 Hz cannot be distinguished by simple circuitry from real cardiac events and may occasionally give rise to uncertain responses.

The state machine of Figure 8.13 is an enhanced version of the basic VVI state machine capable of detecting and responding to the presence of noise. Two new states [N] and [W] have been added. These states affect the sense condition, as well as the way in which the machine returns from the [R] state to the [A] state. The refractory period is now split in two: [R Time Out], which is an absolute refractory, which then proceeds to state [N]–a noise window within which events are sensed but not reported to the VVI state machine. Whenever a sense event occurs within state [N], the moment of occurrence is stored in time stamp variable [TS], but the machine remains in state [N] until a 100-ms timeout