CHAPTER 2

ECG Acquisition, Storage, Transmission, and Representation

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2.1 Introduction

This chapter is intended as a brief introduction to methods for acquiring and storing data. Although it may be tempting for the signal analyst to skip ahead to the chapters concerning the processing of the digital ECG, it is important to understand the etiology of a signal as far as possible. In particular, it is essential to know whether an observed anomaly in the ECG is due to a signal processing step (in either the hardware or software), an electronic artifact, an error in the storage of data, a disturbance on the sensor, or due to a pertinent physiological phenomenon. Furthermore, despite the diligence of the engineer concerning these issues, the error (or success/failure of a particular technique) may simply be due to the selection of the source of data itself.

Toward this end, the present chapter provides an overview of many of issues that should be considered before designing an ECG-based project, from the selection of the patient population, through hardware choices, to the the final signal processing techniques employed. These issues are intricately linked, and choices of one can restrict the analysis at another stage. For instance, choosing (either implicitly or explicitly) a population with low heart rate variability will mean that a higher acquisition sampling frequency is required to study such variability, and certain postprocessing interpolation techniques should be avoided (see Chapter 3). Apart from obvious confounding factors such as age, gender, and medication, variables such as lead configuration and patient activity are also considered.

Errors may creep into an analysis at any and every stage. Therefore, it is important to carefully design not only the hardware acquisition system, but also the transmission, storage, and processing libraries to be used. Although issues such as hardware specification, and relevant data formats are discussed, this chapter is not intended as a definitive or thorough exploration of these fields. However, it is intended to provide sufficient information to enable readers to design their own ECG data collection and storage program with the facility for easy analysis.

Freely available hardware designs and the software to utilize the hardware are discussed, and the electronic form of these designs are available from [1]. This design, although fully functional, cannot be used in a plug-and-play sense due to the serious design and test requirements that are required when attaching a live electrical

circuit to any animal, particularly humans. Furthermore, regulations differ from country to country and change over time. It is, therefore, unwise (and impractical) to list all the required steps to ensure the safety (and legality) of attaching this hardware to any living entity. This chapter does attempt, however, to discuss the major issues connected with ECG acquisition, provide the background to facilitate the design of a useful system, and ensure the associated patient safety issues and regulations can be addressed.

For relevant background reading on hardware and software issues, Mohan et al. [2] and Oppenheim et al. [3] are suitable texts. The reader should also be familiar with the clinical terminology described in Chapter 1.

2.2 Initial Design Considerations

Before describing an example of a hardware configuration for an ECG acquisition system, it is important to consider many issues that may impact the overall design and individual components. Often each choice in the design process impacts on a previously made (perhaps ideal) choice, necessitating an iterative sequence of trade-offs until a suitable compromise is found.

2.2.1 Selecting a Patient Population

Before deciding to collect data, it is important to consider the population demographic and the confounding factors that may complicate subsequent analysis of the ECG. The following issues should be considered when selecting a patient population:

1. *Drugs:* Medication regimens can cause significant differences in baseline cardiovascular behavior. Rapid administration of some drugs can lead to changes in stationarity and confound short-term analysis.
2. *Age:* Significant differences in the ECG are observed between pediatric, young adult, and elderly adult populations.
3. *Gender:* Subtle but important differences in men and women's physiology lead to significant differences. If a study is attempting to identify small variations in a particular metric, the intergender difference may mask these variations.
4. *Preexisting conditions:* A person's past is often the best indicator of what may happen in the future. Using prior probabilities can significantly improve a model's predictive power.
5. *Genetics/family history:* Genetic markers can predispose a subject to certain medical problems, and therefore, genetic information can be considered another method of adding priors to a model.
6. *Numbers of patients in each category:* In terms of learning algorithms, a balanced learning set is often required. Furthermore, to perform statistically accurate tests, sufficient samples are required in each category.

7. *Activity:* Certain medical problems only become apparent at certain activity levels (see Chapter 3). Some patient populations are incapable of certain activities or may experience certain states infrequently. Furthermore, a population should be controlled for individual activity differences, including circadian rhythms.

In clinical investigations it is common to control for items 1 to 4 (and sometimes 5) above, but it is rare that a researcher has the luxury to control for the number of patients. Statistical techniques must therefore be employed to correct for unbalanced data sets or low numbers, such as bootstrap methods.

2.2.2 Data Collection Location and Length

When collecting ECG data from subjects, it is important to consider what the subject pool will easily tolerate. Although hospitalized patients will tolerate numerous recording devices and electrodes, as they recover there is an expectation to reduce the intensity of the recording situation. Ambulatory patients are unlikely to tolerate anything that impedes their normal activity.

Although joining with an existing clinical protocol to fast-track data collection may seem an attractive option (not least because of the extra information and clinical expertise that may be available), it can often be more beneficial to develop experimental recording conditions that allow for greater control and for the adjustment of noise and recording times.

Unrealistic expectations about the quality of data to be collected may lead to a large and expensive data set with low quality ECG information, which requires significant postprocessing. Recommendations for the minimum time for monitoring patients to produce clinically useful data do exist. For instance, Per Johanson et al. [4] indicate that at least 60 minutes of data should be recorded for effective ST analysis. However, if the ST changes are thought to be infrequent (such as in silent ischemia), it is important to perform data collection over longer periods, such as overnight.

In fact, the miniaturization of Holter monitors, coupled with the increasing body of literature connecting cardiac problems with sleep, indicates that home Holter monitoring is a promising option. Recent studies on the ECG during sleep indicate that segmenting ECG data on a per sleep stage basis can significantly increase patient class separation [5, 6]. This approach is essentially the opposite of conventional perturbative experiments such as the Valsalva or stress test, where the patient is forced to an extreme of the cardiovascular system in order to help identify cardiac anomalies under stress. Monitoring during sleep not only provides a low-noise, long-term ECG to analyze but also helps identify cardiac anomalies that manifest infrequently during quiescent activity periods.

Changes in the cardiovascular system due to biological rhythms that extend over days, weeks, and months suggest that long term monitoring may be helpful in preventing these changes confounding an analysis. However, when analyzing extensive ECG records, it is important to develop efficient and reliable algorithms that can easily process such data as well as reliable signal quality indexes to identify and discard noisy segments of data.

2.2.3 Energy and Data Transmission Routes

One additional factor that often influences the population choice is the environment in which the equipment will operate. An ambulatory design means that one must carefully consider power consumption issues, both in terms of how much energy the processor requires to acquire (and process) data and how much energy is required to store or transmit data. Although recent advances in battery technology have made long-term ECG monitoring more feasible, battery technology is still limited, and techniques for reducing power consumption remain important. These include recording infrequent ECG segments (triggered by simple, but not overly sensitive algorithms) and minimizing the number of physical moving parts or the time they are in operation (such as by recording to flash memory rather than removable media, or using *sleep* operations). Furthermore, the addition of new technology, such as wireless data transmission modules, increases power consumption rates.

Sedentary or immobile patients may be more amenable to fixed-location power sources. Therefore, power consumption issues may not be important for this type of population (except for temporary power loss battery back-up considerations). The size of the battery obviously depends on the response time for power restoration. Typically, less mobile patient groups are found within a clinical setting, and therefore, electronic interference issues become more important (see Section 2.5.10).

2.2.4 Electrode Type and Configuration

The interface between an ECG signal source (the patient) and any acquisition device is a system of two or more electrodes from which a differential voltage is recorded. Two electrodes comprise a single lead of ECG. The electrodes may be surface electrodes, which are noninvasive and utilize a conductive gel to reduce skin-electrode impedance. The electrodes may be implanted and therefore have excellent contact (low impedance) and lower susceptibility to motion artifact. The electrodes may also be noncontact, and may sense electromagnetic activity through capacitive coupling. The terminology in this section refers to the clinical lead configuration descriptions given in Chapter 1.

In addition to determining the type of electrodes, one must consider the quantity of electrodes to be used. In diagnostic quality ECG, for example, 12 leads of ECG are acquired simultaneously. Each lead represents a different electrical axis onto which the electrical activity of the heart is projected. One may consider each lead to represent a different spatial perspective of the heart's electrical activity (if we ignore the dispersive effects of the torso upon the signal). If leads are appropriately placed in a multilead ECG, the ensemble of the different waveforms provides a robust understanding of the electrical activity throughout the heart, allowing the clinician to determine pathologies through spatial correlation of events on specific leads.

A variety of lead configurations should be considered, from a full 12-lead setup (with a possible augmentation of the perpendicular Frank leads [7]), a six-lead montage, the reduced Frank or EASI configurations, a simple hospital two- or three-lead configuration (often just lead II and V5), or perhaps just a single lead. Although one would expect that three perpendicular leads should be sufficient to obtain all the electrocardiographic information, the presence of capacitive agents in the torso mean that an overcomplete set of leads is required. Various studies have

been performed to assess the accuracy of diagnoses when using a reduced set of leads and the ability to reconstruct 12-lead information from a lower number of leads.

The standard 12-lead ECG may be derived from the orthogonal Frank lead configuration by the inverse Dower transform [8], and can be useful in many circumstances [9]. Furthermore, the six chest leads (V1 to V6) can be derived from leads I and II by Einthoven's Law [10]. However, the quality of derived leads may not be sufficient for analyzing subtle morphologic changes in the ECG (such as the ST segment). For instance, significant differences in QT dispersion between the Frank leads and the standard 12-lead ECG have been reported [11]. Kligfield [12] points out, there is no consensus regarding which lead or set of leads should be routinely used in QT analysis, in part due to the varying definitions of the end of the T wave,[1] which produce differing results on differing leads.

In general, it seems sensible to assume that we should use as many maximally orthogonal leads as possible.[2] Above this, as many extra leads as possible should be used, to increase the signal-to-noise ratio, noise rejection, and redundancy. However, the anisotropic and nonstationary dielectric properties of the human torso (due to respiratory and cardiovascular activity) mean that spatial oversampling is often required to give an accurate evaluation of clinical features. In other words, multiple leads in similar locations (such as V1 though V6) are often required.

For example, the ST Segment Monitoring Practice Guideline Working Group [13, 14] recommends that if only two leads are available for ST segment monitoring (for patients with acute coronary syndromes), leads III and V3 should be used. If information from a patient's prior 12-lead ECG recorded during an ischemic event indicates that another lead is more sensitive, then this should be used instead of lead III or V3. The working group also states that the best three-lead combination is III-V3-V5. However, many bedside cardiac monitors are capable of monitoring only a single precordial (V) lead because the monitors provide only a single chest electrode. In addition, these two- and three-lead combinations for ischemia exclude lead V1, which is considered the best lead to monitor for detection of cardiac arrhythmias. Furthermore, the use of at least three chest leads (V3, V4, V5) is recommended for ST analysis, to allow noise reduction and artifact identification (although four- or five-lead configurations give better results). In particular, the addition of V2 (which is orthogonal to V5), V6 (which had been shown to be predictive of ischemia), and Y (which is also orthogonal to V5 and V2 [15]) are recommended. A six-lead configuration, and sometimes just a two-lead configuration, can be substituted for the standard 12-lead ECG in certain limited clinical and research applications.[3] It should also be noted that attempts to augment the Frank system with additional leads have led to improved methods for deriving 12-lead

1. Including estimation of the T wave's apparent baseline termination, the nadir of T-U fusion, and extrapolation to baseline from its steepest descending point.
2. There is another approach to lead selection. When there are grounds for suspecting a particular condition with a localized problem, one can choose to use a set of leads that represents a localized area of the heart (clinically known as *lead groups*; see Chapter 1).
3. In particular, where the amplitude of QRS complex is the most important feature, such as in ECG-derived respiration [10, 16].

representations; for example, the EASI lead system, which like the Frank system, is based on the dipole hypothesis of vectorcardiography. The EASI system uses only four electrode sites, the Frank E, A, and I electrode locations, and a fourth electrode location (S) at the manubrium (plus one reference electrode) [17]. Since different leads exhibit different levels of noise under different activity conditions, the choice of lead configuration should be adapted to the type of activity a patient is expected to experience. Electrode configurations that are suitable for sedated hospital patients may not be suitable for ambulatory monitoring. A statement from the American Heart Association (AHA) on exercise standards [18] points out that CM5 is the most sensitive lead for ST segment changes during exercise. CC5 excludes the vertical component included in CM5 and decreases the influence of atrial repolarization, thus reducing false-positive responses. For comparison of the resting 12-lead recording, arm and leg electrodes should be moved to the wrists and ankles with the subject in the supine position.

In 1966, Mason and Likar [19] introduced a variation on the positioning of the standard limb electrodes specifically designed for 12-lead ECG exercise stress testing. To avoid excessive movement in the lead wires attached to the four recording points on the limbs, they suggested shifting the right and left arm (RA and LA) electrodes together with the right and left leg (RL and LL) electrodes. Welinder et al. [20] compared the susceptibility of the EASI and Mason-Likar systems to noise during physical activity. Although they found that the two systems have similar susceptibilities to baseline wander, the EASI system was found to be less susceptible to myoelectric noise than the Mason-Likar system. However, the low number of electrodes used in the EASI system indicates that caution should be used when adopting such a system.

An excellent overview of lead configuration issues and alternative schemes for different recording environments can be found in Drew et al. [14]. Furthermore, they point out the importance of careful electrode preparation and placement. Careful skin preparation that includes shaving electrode sites and removing skin oils and cutaneous debris with alcohol and a rough cloth or preparation gel. This reduces contact impedance and reduces noise in the recording (which can be especially important when attempting to identify subtle morphology changes such as ST elevation/depression).

Electrodes located in close proximity to the heart (i.e., precordial leads) are especially prone to waveform changes when electrodes are relocated as little as 10 mm away from their original location. This can be particularly important for studies which need to be repeated or when electrodes need to be replaced because of signal quality issues or skin irritation.

One method for reducing increasing noise due to electrode degradation and skin irritation is to use noncontact electrodes [21, 22]. These high input impedance electrodes have typical noise levels of $2\,\mu\text{V Hz}^{-1}$ at 1 Hz, down to $0.1\,\mu\text{V Hz}^{-1}$ at 1 kHz, and an operational bandwidth from 0.01 Hz to 100 kHz. Hence, they are well suited to the recording of ECGs. However, the lack of a need for direct skin contact can result in other problems, including artifacts due to movement of the electrode position relative to the body (and heart).

2.2.5 ECG-Related Signals

Recording several ECG leads simultaneously obviously adds extra information to a study, and allows a more robust estimate of noise, artifacts, and features within the ECG. Furthermore, the ECG is strongly related to the respiratory and blood pressure signals (see Chapter 4). It can be advantageous, therefore, to either derive surrogates for these coupled signals from the ECG or to make direct simultaneous recordings of related signals.

A nonexhaustive list of the major information sources related to the ECG that one should consider is as follows:

- *Respiration:* This can be derived from the ECG (see Chapter 8) or measured directly from strain-bands around the torso, nasal flow-meters, or impedance pneumography. Impedance pneumography involves measuring the differential impedance changes (at kilohertz frequencies) across two of the ECG electrodes that have been altered to inject a small current through the patient at this frequency. For ECG-derived respiration (EDR) [16], the best set of electrodes for deriving respiration depends on whether you breathe from the chest or from the diaphragm. Furthermore, if respiratory sinus arrhythmia is present, respiration can also be derived from the dominant high-frequency component of the RR interval time series (see Chapter 3), although this is less reliable than morphology-based EDR.
- *Blood pressure (BP):* This can be measured invasively via an arterial line or noninvasively through periodic pressure cuff inflations. Relative BP measures include the Finapres and pulse transit time (the time from the R-peak on the ECG to a peak on a pulsatile pressure-related waveform).
- *Activity:* Often studies attempt to control for the intersubject and intrasubject variability due to activity and circadian rhythms a patient experiences. Unfortunately, the activity due to the uncontrollable variable of mental activity can often lead to a larger interpatient and intrapatient variability than between patient groups and activities [5]. A good method to control for both mental and physical activity is to use some form of objective measure of level of consciousness. Although none exists for conscious subjects, electroencephalogram (EEG)-based scales do exist for sleep [23] and sedation [24]. Recent studies have shown that controlling for mental and physical activity in this manner leads to a more sensitive measure of difference between cardiovascular metrics [5]. Studies that attempt to stage sleep from heart rate variability (HRV) have proved inconclusive. Conversely, although heart rate artifacts can be observed in the EEG, the broadness of the artifact (and its origin from an arterial pressure movement) are such that accurate HRV cannot be accurately assessed from the EEG. However, recent work on cardiorespiratory coupling in sleep has shown that sleep staging from the ECG is possible.
- *Human-scored scales:* It is important to consider whether a human (such as a nurse or clinician) should be present during some or all of the experiments to make annotations using semiobjective scales (such as the Riker Sedation/Agitation Scale [24]).

2.2.6 Issues When Collecting Data from Humans

When collecting data from humans, not only should the patient population demographics be considered, but also the entire process of data collection, through each intermediate step, to the final storage location (presumably on a mirrored server in some secure location). The following major issues should be seriously considered, and in many cases, thoroughly documented for legal protection:

1. *IRB/ethics board approval:* Before any data can be collected, most institutions require that the experimental protocol and subsequent data use be preapproved by the institutional review board (IRB) or institutional ethics committee.
2. *Device safety:* If the device is not a commercially FDA/EC (or equivalent) approved device, it must be tested for electrical safety (including electrical isolation), even if the design is already approved. The institution at which data are being collected may require further electrical tests on each unit to be used within the institution. (See Section 2.5.10.)
3. *Patient consent:* If collecting data from humans, it is important to investigate whether data being collected is covered under an existing IRB approval (and there is no conflict with another study) and whether explicit consent must be collected from each patient.
4. *Future uses of data:* It is important to consider whether data may be used in other studies, by other groups, or posted for open dissemination. It is often easier to build in relevant clauses to the IRB at the onset of the project rather than later on.
5. *Traceability and verification:* When collecting data from multiple sources, (even if this is simply ECG plus patient demographics) it is important to ensure that the paired data can be unambiguously associated with relevant "twin(s)." Integrity checks must be made at each storage and transfer step (e.g., by running the Unix tool *MD5SUM* on each file and comparing it to the result of the same check before and after the transfer).
6. *Protected health information (PHI):* It is essential, however, that the individuals being monitored should have their identity thoroughly protected. This means removing all PHI that can allow someone using public resources to identify the individual to whom the ECG (and any associated data) belongs. This includes pacemaker serial numbers, names of relatives, and any other personal identifiers (such as vehicle license numbers). Date-shifting that preserves the day of the week and season of the year is also required.
7. *Data synchronicity:* When collecting data over a network, or from multiple sources, it is important that some central clock is used (which is constantly being adjusted for clock drift, if absolute times are required). It is also important to consider that most conventional operating systems are not intended for real-time data acquisition and storage. (In fact, for life-critical applications, only certain processors and operating systems are allowable.) Although there are methods for adjusting for clock drift (such as averaging independent clocks), standard OS distributions such as Linux or Windows are inadvisable. Rather, one should choose a real-time operating systems (RTOS) such as LynxOS, which is used in the GE/Marquette patient

monitors, or a real-time kernel such as Allegro. Care should also be taken to mitigate for time differences caused by daylight savings.

8. *Data integrity:* The collected data must be stored securely (in case any PHI was not removed) and safely. In other words, data should be backed up in two geographically separate locations using a RAID storage system, which is regularly checked for disk integrity. This is particularly important for long-term data storage (on the order of a year or more) since individual hard disks, CDs, and DVDs have a short shelf life. Magnetic tape can also be used, but data access can be slow.
9. *Storage capacity and file size limits:* If certain file size limits are exceeded, then problems may result, not only in the online writing of the file to disk but in subsequent transfers to disk or over a network. In particular, upper limits of 500 MB and 2 GB exist for single files on DOS-based disks and DVD storage, respectively. Furthermore, the larger the file, the more likely there will be errors when transferring data over networks or writing to other media. It should also be noted that, currently, none of the writable DVD formats are fully compatible with all drive types.
10. *Resolution, dynamic range, and saturation:* Sufficient frequency resolution and dynamic range in the amplification (or digital storage) of ECG data should be specified. For example, if the data storage format is limited to 12 bits, a 2-mV signal on the input should correspond to 10 bits or less in the digital recording. It is important not to be too conservative, however, in order to ensure that the amplitude resolution is sufficient for the signal processing tasks.
11. *Data formats:* When storing data, it is important to use an accurate and verifiable data format (at each step). If data are to be converted to another format, the method of conversion should be checked thoroughly to ensure that it does not introduce errors or remove valuable information. Furthermore, a (final) data format should be chosen that allows the maximum flexibility for data storage, transmission, access, and processing.
12. *Electronic security:* In the United States, new legislation requires that any researchers transmitting or storing data should do so in a secure manner, enabling the correct security mechanisms at each step and keeping an access log of all use. Users should be required to sign a data use/privacy contract in which they agree not to pass on any data or store it in an nonsecure manner. The latter phrase refers in particular to removable media, laptops, and unencrypted hard drives (and even swap space).
13. *Availability of data:* It is also important to consider how frequently data can be collected and at what rate to ensure that sufficient transmission bandwidth is guaranteed and storage capacity is available.

2.3 Choice of Data Libraries

The choice of libraries to store the ECG data may at first glance seem like a peripheral subject of little importance. However, poor choices of storage format can often lead to enormous time-sinks that cause significant delays on a project. Important

questions to ask when choosing a data format and access libraries include:

- What are the data going to be used for?
- Are the data format and libraries extensible?
- Is the data format compact?
- Are the libraries open-source?
- Do the libraries and format support annotations?
- Is the format widely accepted (and well tested)?
- Can I easily (and verifiably) de-identify my data using this format?
- Are the libraries for reading and writing data available for all the operating systems on which the ECG will be analyzed?
- Are there additional associated libraries for signal processing freely available?
- Can the libraries be used in conjunction with all the programming languages you are likely to use (C, Java, Matlab, Perl)?
- Are there libraries that allow the transmission of the data over the Internet?
- Are there libraries that allow me to protect access to the data over the Internet?
- Can the data format be easily converted into other data formats that colleagues might require for viewing or analysis?

Clinical formats that are in general use include: the extended European Data Format (EDF+) [25], which is commonly used for electroencephalograms (and more increasingly is becoming the standard for ECGs); HL7 [26, 27] (an XML-based format for the exchange of data in hospitals); and WaveForm DataBase (WFDB), a set of libraries developed at MIT [28, 29]. HL7 is by nature a very noncompact data format that is better suited to the exchange of small packets of data, such as for billing. Despite this, the FDA recently introduced an XML-based file standard for submitting clinical trails data [30, 31]. The main rationale behind the move was to unify the submission format (previously PDF) for what are essentially small amounts of data.

A recent attempt to improve on this format and integrate it with other existing waveform reading libraries, such as WFDB, is ecgML [32]. Although EDF+ solves some of problems of EDF (such as the lack of annotations), it is still restrictive on many levels and is not well supported under many different languages. Furthermore, it is not easily extensible, and does not cope well with sudden changes in the data format. In contrast, WFDB is a suite of libraries for accessing many different data formats and allows positive answers to the above questions. WFDB records have three main components; an ASCII header file, a binary data file, and a binary annotation file. The header file contains information about the binary file format variety, the number and type of channels, the lengths, gains, and offsets of the signals, and any other clinical information that is available for the subject. The separate header file allows for rapid querying. Similarly, any number of annotation files can be associated with the main binary file just by using the same name (with a different extension). Again, rapid reading of the annotations is then possible, without the need to seek around in a large binary file. Furthermore, WFDB allows the virtual concatenation of any number of separate files, without the need to actually merge them.

Past and recent developments that set WFDB apart from other data reading and writing libraries include:

- The ability to read data over HTTP protocols;
- The extensibility of the annotations format to allow the use of defined labels and links to external documents, including the use of hypertext links;
- The inclusion of *libcurl* libraries to allow access to secure data behind password protected sites;
- The ability to seamlessly cope with changes in signal gain, sampling frequency, lead configuration, data dimensionality, and arbitrary noncontiguous breaks in the record;
- The flexibility to work with many data formats (arbitrary dynamic ranges, resolutions, byte order, and so forth);
- The development of open-source signal processing libraries that have been well tested and documented;
- Supported libraries for multiple programming languages, such as C, Java, Matlab, and Python (using *SWIG* wrappers), on multiple platforms;
- Conversion tools between other standard formats (EDF, ASCII) and between sampling frequencies.

WFDB, therefore, is an excellent (if not the best) current choice for storing ECG data. Another parallel resource development, intricately connected with WFDB, is libRASCH [33]. This is a set of cross-platform C-based libraries that provides a common interface to access biomedical signals, almost regardless of the format in which they are stored. Many proprietary biomedical signal formats are accessible through this set of libraries, which work with a wide variety of languages (Perl, Python, Matlab, Octave, and SciLab). The libraries are modular, based upon an Application Programming Interface (API), that allows the easy addition of *plug-ins*. Therefore, it is easily extensible for any new data formats, programming languages, viewing tools, or signal processing libraries. A set of signal processing plugins are available for this tool, including fetal heart rate analysis, heart rate turbulence, and other more standard heart rate variability metrics. See Schneider [33] for more information on libRASCH.

2.4 Database Analysis—An Example Using WFDB

Before performing any data collection, or more frequently during data collection, it is important to test proposed algorithms on freely available (annotated) data, using standard tools and metrics. Without such data and tools, it is impossible to judge the scientific merit of a particular approach, without reimplementing the research completely.[4]

Over recent years, advances in hardware technology have made the acquisition of large databases of multichannel ECGs possible. The most extensive and freely available collection of ECG (and related) waveforms can be found on PhysioNet [28] (the MIT Laboratory for Computation Physiology's Web site) or one of its many

4. Furthermore, since it is extremely difficult and time-consuming to reproduce an algorithm in its entirety from a short paper, the posting of the code used to generate the quoted results is essential.

mirrors. This collection of databases comprises hundreds of multilead ECGs recorded from patients who suffer from various known heart conditions, as well as examples of healthy ECGs, for periods from 30 minutes to more than a day. These records have been annotated by expert clinicians and, in some cases, verified by automatic algorithms to facilitate the further evolution of diagnostic software.

Tools, available from the same location, enable the researcher to call libraries that read and compare the clinician-annotated or verified files for each patient with a number of freely available clinically relevant algorithms (such as QRS detection, ECG-segmentation, wave onset location, and signal quality) or any self-created algorithm, using the WFDB data reading libraries. The database and libraries of comparative tests conform to the relevant American National Standards Institute (ANSI) guidelines [34] developed by the Association for the Advancement of Medical Instrumentation (AAMI) [35]. Furthermore, medical devices that use a QRS and arrhythmia detection algorithm must quote performance statistics on the MIT-BIH database.

Each patient record in the MIT-BIH database, labeled 100 to 124 and 200 to 234, consists of 30 minutes of ECGs sampled at 360 Hz with 16 bit accuracy and labeled by experts. These records can be antialias upsampled or downsampled using the WFDB tools[5] to any required frequency and resolution. The WFDB tools account for any changes caused by the downsampling (such as aliasing and annotation timing differences) and generate header files to allow synchronization of the labels with the new data files. The clinicians' annotations consist of the following labels for each beat[6]:

- V—Ventricular Ectopic Beat (VEB): a ventricular premature beat, (such as an R-on-T[7]), or a ventricular escape beat.
- F—Fusion Beat: a fusion of a ventricular and a normal beat.
- Q—Paced Beat: a fusion of a paced (artificially induced) and a normal beat or a beat that cannot be classified.
- S—Supraventricular Ectopic Beat (SVEB): an atrial or nodal (junctional) premature or escape beat, or an aberrant atrial premature beat.
- N—Normal: any beat that does not fall into the S, V, F, or Q categories. This category also includes Bundle Branch Block Beats (BBBB) which give a widened QRS complex and can be indicative of myocardial infarction.[8] However, the broadening is very hard to detect.
- X: a pseudo-beat label generated during a segment marked as unreadable.
- U: marks the center of unreadable data segments, beginning 150 ms after the last beat label and 150 ms before the next.

5. The *xform* executable.
6. A full list, including arrhythmia onsets and noise labels, can be found at [36].
7. A potentially dangerous condition is induced when a premature ventricular contraction occurs during the T wave of the preceding QRS-T complex. R-on-T phenomenon can induce ventricular tachycardia or ventricular fibrillation.
8. A blockage in the normal conduction paths of the heart that leads to permanent damage to the heart muscle.

- [and]: Rhythm labels marking the onset and cessation of ventricular fibrillation or flutter (VF), respectively.

Note that beat labels are never paired with rhythm labels, and beat labeling is discontinued between these labels. Incorporation of the WFDB libraries into an algorithm that a user wishes to test enables the generation of a test annotation file of time-stamped event labels in a comparable format to the clinician annotation files. When the WFDB tools are run on these files a beat-by-beat comparison is performed, and an output file is created that compares the time-scoring of events. Two events are held to be simultaneous (by the ANSI standards [35]) if they occur within ±150 ms of each other. Thus, in order to perform beat-by-beat comparisons, a pseudo-beat label 'O' is generated any time the test algorithm labels a point in the ECG as a beat and there is no clinician scored label within 150 ms.

Table 2.1 is a typical file generated by these tools[9] for scoring the results from a standard, freely available, QRS detector,[10] that was applied to the MIT-BIH arrhythmia database. Columns 2 to 12 refer to the beat-by-beat scoring with a capitalized label denoting the actual event (as labeled by the clinicians) and the lower-case letter denoting the labeling provided by the algorithm under test. Nn′, Vn′, and Fn′ are thus the number of normals, VEBs, and fusion beats that the test algorithm labeled as normals, respectively. On′ is the number of normal pseudo-beats that the algorithm generated (a "normal" label being generated when there was no beat there). Nv′ and Vv′ are, respectively, the numbers of normals and VEBs that have been labeled as VEBs. Fv′ is the number of fusion beats labeled as VEBs, and Ov′ is the number of pseudo-VEB labels (a VEB label being generated by the algorithm when no beat at all occurred in the original).[11] No′, Vo′, and Fo′ are the number of pseudo-beats generated in the test annotation file for the cases when there was a normal, VEB, or fusion beat in the original ECG, but the algorithm failed to detect such a beat.

Thus, the records are scored with the number of false positives (FP; beats identified by the algorithm when the clinician has not scored one), false negatives (FN; beats missed by the algorithm when the clinician has scored one), and true positives (TP; both annotations agree on the time of the event). These are defined as[12] TP = Nn′ + Vn′ + Fn′, FN = No′ + Vo′ + Fo′, and FP = On′. The second-to-last column in Table 2.1 is Q Se, which gives the sensitivity of the algorithm, or the number of TPs as a percentage of the total that really exist. The last column gives the positive predictivity, Q + P, or the number of TPs as a percentage of the number detected by the algorithm. These two parameters are therefore calculated

9. The "bxb," beat-by-beat comparison algorithm in particular.
10. These results were generated using the author's own C-code version of the Pat Hamilton's QRS detector [37, 38]. The latter has now been improved and is freely available [39]. There is also a Matlab version which works in a batch manner, available from this book's accompanying Web site [1].
11. Note that these latter four columns are zero in this example since the example algorithm was not designed to classify, and all beats are assumed to be normal sinus beats.
12. Beat type classification is detailed in the output file, but incorrect classification (such as labeling a VEB as a normal) does not affect the statistics; they are based on how many QRS complexes are detected regardless of their classification.

Table 2.1 Standard Output of PhysioNet's *bxb* Algorithm for a Typical QRS Detector (Subjects 109 Through 222 Omitted)

Record	*Nn′*	*Vn′*	*Fn′*	*On′*	*Nv′*	*Vv′*	*Fv′*	*Ov′*	*No′*	*Vo′*	*Fo′*	*Q Se*	*Q+P*
100	1901	1	0	0	0	0	0	0	0	0	0	100.00	100.00
101	1521	0	1	4	0	0	0	0	0	0	1	99.93	99.74
103	1725	0	0	1	0	0	0	0	4	0	0	99.77	99.94
105	2117	29	4	133	0	0	0	0	4	0	1	99.77	94.17
106	1236	459	0	1	0	0	0	0	0	1	0	99.94	99.94
108	1461	13	2	257	0	0	0	0	4	0	0	99.73	85.17
...	...	...	...	...	...	...	...	...	...	...	...	...	...
...	...	...	...	...	...	...	...	...	...	...	...	...	...
...	...	...	...	...	...	...	...	...	...	...	...	...	...
223	1736	447	8	1	0	0	0	0	0	8	0	99.64	99.95
228	1225	300	0	49	0	0	0	0	176	2	0	89.55	96.89
230	1858	1	0	1	0	0	0	0	0	0	0	100.00	99.95
231	1278	0	0	1	0	0	0	0	0	0	0	100.00	99.92
232	1485	0	0	5	0	0	0	0	0	0	0	100.00	99.66
233	1862	688	6	1	0	0	0	0	1	4	0	99.80	99.96
234	2288	0	0	1	0	0	0	0	0	3	0	99.87	99.96
Sum	77011	5822	623	774	0	0	0	0	427	78	15		
Gross												99.38	99.08
Average												99.33	99.06

Note that all beats detected have been assumed to be normals, since no beat classification has been performed.

as follows:

$$\text{Q Se} = \frac{\text{TP}}{\text{TP} + \text{FN}} = \frac{\text{Nn}' + \text{Vn}' + \text{Fn}'}{\text{Nn}' + \text{Vn}' + \text{Fn}' + \text{No}' + \text{Vo}' + \text{Fo}'} \tag{2.1}$$

$$\text{Q} + \text{P} = \frac{\text{TP}}{\text{TP} + \text{FP}} = \frac{\text{Nn}' + \text{Vn}' + \text{Fn}'}{\text{Nn}' + \text{Vn}' + \text{Fn}' + \text{On}'} \tag{2.2}$$

From Table 2.1 one can see that patient 100's heart beat 1,902 times over the 30-minute period, an average heart rate of 63.4 bpm. All the beats were classified as normals by the algorithm (nonzero entries in the second, third, and fourth columns), although one of these beats was actually a VEB. For this record, the Q Se and Q + P are therefore both 100% for the algorithm under test.

Note that the algorithm labeled patient 101's ECG as containing 1,522 normals. All the beats were actually normal except one fusion beat. However, four normals were detected by the algorithm when there were no actual beats present. Thus, the sensitivity is $\frac{1521+1}{1521+1+4} = 0.9974$ or 99.74%. Furthermore, one fusion beat was missed since a pseudo-beat was generated from the WFDB annotation file ($\text{Fo}' = 1$). Thus, positive predictivity is reduced to $\frac{1521+1}{1521+1+1} = 0.9993$ or 99.93%. Patient 103 has a total of 1,729 beats. All these beats were normal, but four were missed by the algorithm. Only one beat was labeled as a normal and did not actually occur. It is important to note that the ANSI standards [34] allow 5 minutes of adjustment and adaptation for any algorithm being tested, and therefore, the first 5 minutes of data are not included in the results generated by the WFDB tools. The average performance over all the files is usually quoted as the *gross* or average (Av). Note

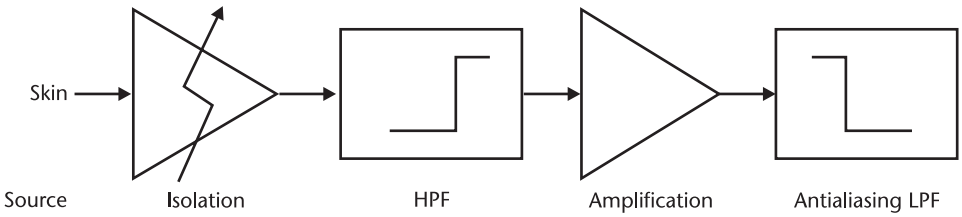

Figure 2.1 Simplified diagram of hardware setup. The fluctuations in PD between the differential ECG leads on the skin's surface (or sometimes inside the body) are amplified with an optically isolated instrumentation amplifier. The signal is then passed through a HP filter, a second amplification stage, then a lowpass antialiasing filter. The signal is finally sampled by an A/D card (not shown). The opto-isolation can also be moved so it occurs after the final A/D stage.

that the values of 99.33% sensitivity and 99.06% positive predictivity for this implementation of this algorithm is comparable to that of the original Hamilton, Pan, and Tompkins algorithm [37, 38]. The latest version of their algorithm [39] reports average Q Se and Q + P values of 0.9977 and 0.9979, respectively, which compare well to state-of-the-art QRS detectors. Excellent surveys and comparative analyses are available on this topic [40–42].

2.5 ECG Acquisition Hardware

In this section, the issues surrounding the design and fabrication of a hardware unit for ECG signal conditioning are discussed. More detailed information is available from the book's companion Web site [1], together with example schematics and PCB layouts. The reader is also referred to Mohan et al. [2] and Oppenheim et al. [3] for more detailed theory.

2.5.1 Single-Channel Architecture

Figure 2.1 illustrates the general process for recording an ECG from a subject. The (millivolt) fluctuations in potential difference (PD) between the differential ECG leads on the skin's surface (or sometimes inside the body) are amplified with an optically isolated instrumentation amplifier (see Figure 2.2). Note that, in general, three leads are required for one differential signal from the subject since a ground electrode (Input C) is also required.[13] The voltage difference between the other electrodes (Inputs A and B) serves as the signal input that is amplified through the op-amps U1A and U1B. These signals are then differentially amplified and passed through a highpass filter (such as an eighth order Bessel filter).

By using a suitable design tool (such as Orcad/PSpice [43]) or free software (such as PCB123 [44]), this schematic can be converted into a printed circuit board (PCB) schematic with all the relevant microchip dimensions specified. Fabrication services

13. In fact, there are two basic lead types: bipolar and unipolar. Bipolar leads (the *standard limb leads*) use one positive and a one negative electrode. Unipolar leads (the *augmented leads* and *chest leads*) have a single positive electrode and use a combination of the other electrodes to serve as a composite negative electrode.

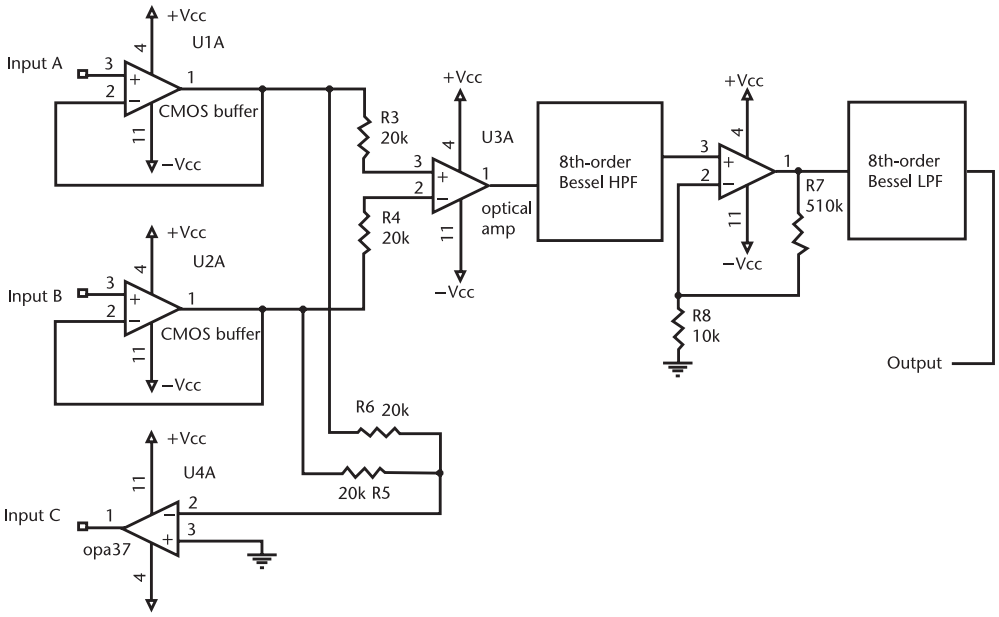

Figure 2.2 Circuit diagram for acquiring a single lead ECG signal. One electrode (Input C) serves as ground while the voltage difference between the other electrodes (Inputs A and B) serves as the signal input. Eighth-order Bessel (HP) filters are used to minimize noise, with minimal distortion.

for a PCB are cheap and rapid, therefore alleviating the need for in-house production. An example of a PCB design can be found on this book's accompanying Web site [1].

2.5.2 Isolation and Protection

For any circuit that uses a significant power source (such as mains electricity) and that comes into contact with a human, the board must be segmented into isolated and nonisolated sections. These sections must be separated by approximately 10 mm (or more) of free space or circuit board from each other (depending on the dielectric constant of the board). Even tiny amounts of current leakage (less than 100 μA [45]) through the subject can induce lethal ventricular fibrillation in catheterized human subjects.

The power from the directly (mains) powered nonisolated section of the board is transferred to the isolated section of the board using DC-to-DC converters. The use of a transformer to use magnetic induction to transfer the power results in only the transfer of photons, rather than electrons (and hence current) to the isolated region of the board. There is, therefore, no current path to the monitored subject from the mains power. The voltages in the figures in this chapter are denoted $\pm$Vcc regardless of whether they are on the isolated or nonisolated side of the board. However, $\pm$Vcc on the isolated side is not connected to $\pm$Vcc on the nonisolated side.

Similarly, information is transmitted back from the isolated (patient) side of the circuitry to the nonisolated side via light in the opto-isolators. Opto-isolators convert electrons (current) into photons and back into electrons, thereby transmitting only light (and not current) across the isolation gap. The opto-isolators are placed

such that they span the 10-mm gap between the isolated and nonisolated sections of the board and are powered on either side by either the isolated output of the DC-to-DC converters or the live mains power, respectively. See [2] for more information.

After the opto-isolation stage, the signal is then passed through a highpass (HP) filter, a second amplification stage, then a lowpass (LP) antialiasing filter. The signal is finally sampled by an analog-to-digital (A/D) conversion card.[14] The details of each of these stages are discussed below.

Note that resistors with extremely high values should also be placed between each input and ground for static/defibrillation voltage protection. Furthermore, a current limiting resistor at output is required in case the op-amps fail. These components are not shown in the diagrams in this chapter. It should also be noted that optical isolation in an early stage of amplification can introduce significant noise. It is, therefore, often preferable to isolate directly after digitizing the signal.

2.5.3 Primary Common-Mode Noise Reduction: Active Grounding Circuit

Power-line, or mains, electromagnetic noise (and to a lesser extent harmonics thereof) is ubiquitous indoors, since electrical systems in buildings utilize AC power delivered at these frequencies. The spectrum of some ECGs (murine, for example) can span from DC to 1 kHz, and therefore, using a 50-Hz to 60-Hz notch filter to remove mains noise will invariably remove at least some signal content.[15] An active ground circuit (illustrated in Figure 2.3) is the preferred means of removing such common-mode noise.

The active grounding circuit, shown in Figure 2.3, works by taking the average (common mode) of the voltages at the two input terminals of the preamplification stage. It then amplifies and inverts the signal, and then feeds the resultant signal back as the ground, or reference voltage, for the circuit. The circuit does not remove differential signal content but mitigates common-mode noise. That is, it removes the part of the signal that is simultaneously present on both electrodes.

2.5.4 Increasing Input Impedance: CMOS Buffer Stage

High input impedance is requisite in a biomedical instrumentation design, as the signals of interest (particularly electro-physiological signals) are extremely weak (on the order of several hundred microvolts) and, consequently, cannot supply substantial current. An extremely high input impedance and corresponding power amplification is an inherent property of a CMOS circuit. A CMOS preamplifier op-amp circuit, therefore, serves as an ideal decoupling stage between the weak electrophysiological signal and subsequent analog signal processing circuitry.

14. The A/D card is not shown in Figure 2.1. Recommendations for possible cards can be found on this book's accompanying Web site [1].
15. The width of the notch must be at least 2 Hz since the frequency of the interference is not constant.

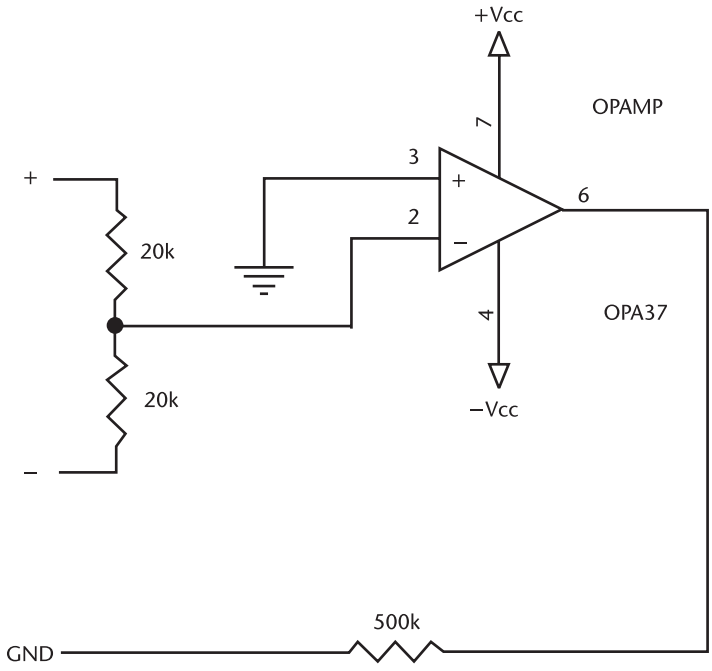

Figure 2.3 Active ground circuit used for common-mode noise reduction. The common-mode signal at the input electrodes is inverted and fed back through a current-limiting resistor (for subject projection). This circuit is particularly useful in reducing prevalent mains noise, which is capacitively coupled into both signal input wires. GND indicates ground. (*After*: [46].)

2.5.5 Preamplification and Isolation

Although it is preferable to place the isolation step after the amplifiers, this means that the user must write their own drivers for the A/D controllers. If subtleties in the ECG, such as late potentials, are not important, then it is possible to provide optical isolation at the preamplification stage. This ensures that an electrical surge within the instrumentation circuitry cannot electrocute the subject, and conversely, a surge at the input terminals will not damage instrumentation circuitry beyond the preamplifier. The strongest source of such currents originates from capacitive coupling through the power supply to the grounded instrumentation chassis. However, if the chassis that houses the ECG hardware is properly grounded, the minimal resistance of the case to ground will lead most of the current to sink to ground through this pathway. The optical isolation amplifier discussed in this section provides a very high dielectric interruption, or equivalently a very small capacitance, in series between the lead wire and instrumentation, protecting the subject from acting as a pathway for leakage current to ground.

The physiological voltages produced by mammal hearts are on the order of 100 μV to several microvolts, and the dynamic range of the preamplifier is usually $\pm$12V DC. Accounting for different half-cell potentials in the electrodes that could produce a differential DC voltage as high as 100 mV, an expected a gain of 25 is appropriate for the preamplification stage provides an adequate SNR and, upon reaching steady-state, does not saturate. However, care must be taken as higher

PDs might be encountered in some situations (such as extreme baseline wander in exercise, for example), and a lower gain may be appropriate.

2.5.6 Highpass Filtering

The output signal from the instrumentation amplifier is input to an eighth-order Bessel HP filter with a cutoff frequency of 0.1 Hz. Note that for ST analysis, a cutoff of 0.05 Hz is required (see Chapter 10), and other evidence indicates that useful information exists down to 0.02 Hz [47]. This HP filter serves to remove the DC offset due to half-cell potential differences in the electrodes as well as other low-frequency signal noise (mostly baseline wander). The choice of a Bessel transfer function is motivated by the fact that it has optimal phase response. That is, it has the desirable property of near-constant group delay, and negligible phase distortion. This optimality in phase response comes at the price of decreased roll-off steepness in the transition band relative to other transfer functions.

2.5.7 Secondary Amplification

After passing through the HP filter, the signal is again amplified; this time by a gain of 52 in the arrangement illustrated in Figure 2.4. This is the final amplification stage in the signal conditioning pipeline. This second amplification stage further increases the SNR of the signal and boosts the signal voltage to a range appropriate for sampling with an A/D converter with a dynamic range of $\pm$10V. The amplification circuit (Figure 2.4) is a simple feedback op-amp network utilizing the familiar gain equation $1 + Rf/R_{in}$, where in this system $Rf = 510\,\text{k}\Omega$ and $R_{in} = 10\,\text{k}\Omega$, to provide the gain factor of 52. The signal entering this amplification stage, in contrast with that entering the preamplification stage, is not offset due to half-cell potential differences and baseline drift because of the preceding HP filter stage. As such, this amplification stage can comfortably amplify the signal by the rather sizable factor of 52 without saturating the amplifiers.

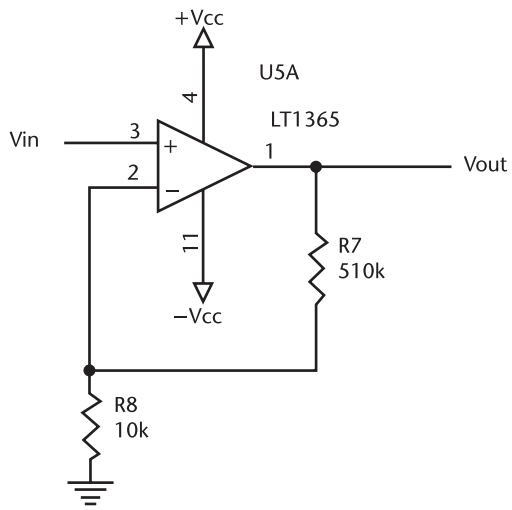

Figure 2.4 A noninverting negative-feedback op-amp with a gain of 52 (determined by the ratio of the 510 kΩ to 10 kΩ resistors).

2.5.8 Lowpass Filtering and Oversampling

Since the ECG spectrum may occupy the DC to 1 kHz [48], the Nyquist sampling criterion mandates that, with an *ideal* LP filter with a passband of 0 to 1 kHz one should sample the signal at 2 kHz to avoid aliasing. Since a circuit filter implementation is never ideal, one must enforce a relationship between the filter type, the filter's cutoff frequency, and the A/D sampling rate that produces an acceptably small amount of aliasing. The filter transfer function for the LP filter, as for the HP filter, was chosen to have a Bessel transfer characteristic to minimize phase distortion. This optimization for phase response comes at the expense of a slow roll-off in the transition region.

Oversampling is a technique often employed in systems using an antialiasing filter with relatively slow roll-off. It can be shown that sampling of an analog signal produces spectral copies of the analog spectrum at multiples of the sampling frequency, f_s, in the discrete-time frequency domain [3]. Consider the example in which a signal is filtered in the analog domain with a nonideal LP filter of cutoff 1 kHz, then sampled at 2 kHz. The result is an aliased signal, which is manifested in overlapping spectral regions in Figure 2.5. One might consider building a higher-order analog filter to reduce the transition band, which would prove costly and time-consuming, to mitigate the effects of aliasing. Alternatively, one could sample the signal at a faster rate, thereby spreading the spectral copies further apart, as Figure 2.6 illustrates. Of course, a high-order digital filter, which is cheap and relatively simple to implement, can be used to LP filter the digitized signal, followed by simple decimation. This achieves the same effect as with a high-order antialiasing filter, without the hardware complexity.

Such a technique, known as oversampling, is often employed in data-sampling systems to minimize the complexity and cost of analog circuitry and harness the power of fast digital processing power. In the case of this system, a high-order antialiasing filter is used. However, since the filter is optimized for minimal phase distortion, its roll-off is similar to that of a lower-order filter. A reasonable

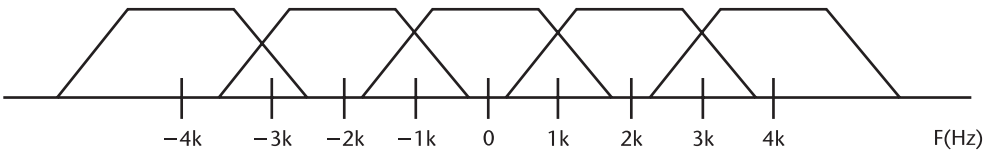

Figure 2.5 A signal band-limited to approximately 1.75 kHz (due to slow roll-off of 1 kHz cutoff Bessel antialiasing analog filter) sampled at 2 kHz has spectral copies at multiples of 2 kHz and suffers aliasing (overlapping regions).

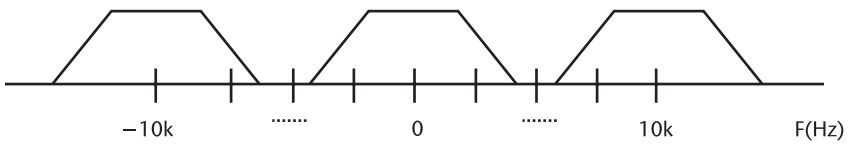

Figure 2.6 The same signal, band-limited to approximately 1.75 kHz (due to slow roll-off of 1 kHz cutoff Bessel antialiasing analog filter) sampled at 10 kHz (5× oversampling) has spectral copies repeating at multiples of 10 kHz and does not suffer aliasing.

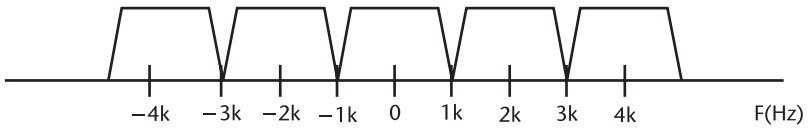

Figure 2.7 After applying a high-order digital lowpass filter then decimating by a factor of 5, the spectra are spaced by multiples of 2 kHz but with no aliasing. This combination of digital LP filtering and decimation prevents the need for an expensive analog antialiasing filter.

approach for this type of signal is to employ five-times oversampling, so that the signal is sampled at five times the Nyquist rate of 2 kHz. After being sampled at this high rate, the signal can then be digitally LP filtered and decimated[16] by a factor of five to give an effective sampling rate of 2 kHz. A symmetric digital LP FIR filter preceding the decimation avoids aliasing. The initial use of oversampling also minimizes aliasing, and subsequent downsampling (after LP filtering) provides the minimum allowable lossless data storage requirement without resorting to compression. Figure 2.7 shows the spectral content of a signal after it has been oversampled (five times), digitally LP-filtered, then decimated by a factor of five. The spectral copies do not overlap, indicating that no aliasing has occurred. However, the spectra are closely spaced, indicating that the signal is not oversampled, and disk storage space is minimized.

2.5.9 Hardware Design Issues: Sampling Frequency Choice

The hardware implementation described so far is an example of how one might choose to design an ECG acquisition system. Of course, variants of this design are likely to be more useful to a specific application. Some general guidelines in designing such a system should be followed. First, when selecting filter components, ensure that they are functional over the entire frequency range (particularly down to 0.05 Hz or lower if you are designing an application that requires ST analysis or apnea detection; see Section 2.5.6). Second, it is important to consider the resonant frequencies of the components chosen for the design. Third, the cable shielding should be terminated at an isolated ground or, preferably, to the board enclosure. If the cable shield is terminated to an isolated ground using a small capacitor from the isolated ground to the enclosure ground, CM interference is reduced. Finally, the circuit board layout should be such that the coupling between components is minimized.

The designs illustrating this chapter provide for a sampling frequency of 2 kHz. Although this sampling rate might seem to be rather high, (except for high-frequency ECG applications analysis such as late potentials [49–52]), it has been shown that a sampling rate of at least 500 Hz (and sometimes 1 kHz) is required for applications such as heart rate variability and PR interval variability analysis [53–55]. In general, when recording the ECG of an animal smaller than a human, the ECG may extend to even higher frequencies. Therefore, a sampling rate of 2 kHz may be too low for

16. Really this is semidecimation, since decimation strictly means keeping every tenth item; here we twist the meaning slightly and keep every fifth sample.

some applications, and changes to the hardware (in the oversampling stage) may be required. However, even in murine studies, a sampling rate of 2 kHz is considered sufficiently high [48].

The system design described above is available from the Web site that accompanies this book [1]. However, this circuit should not be used on living entities without further tests. The next section outlines many of the issues that must be addressed before live subject data acquisition can commence.

2.5.10 Hardware Testing, Patient Safety, and Standards

Once fabricated and tested for basic functionality, it is important to test that a wide range of ECG signals will not be distorted by the acquisition system. There are several ways to achieve this. For instance, the transfer function for the system can be experimentally derived by using a signal generator to pump a range of frequencies with known amplitudes into the input electrodes and compared with the output response. However, the inevitable imperfections in this derived transfer function do not give a direct understanding of how significantly distorted clinical metrics derived from the ECG may be. In order to test such a system, one may choose to drive the inputs with either a database of representative signals or an artificial ECG-like signal. Although the former approach provides a realistic range of data (using a variety of known databases), there is an inherent noise component in the signal which confounds any measure of fidelity. The difficulty in measuring the clinical parameters in such data further confounds the problem. Furthermore, the use of a particular database may bias the performance results. Unrepresentative, yet perhaps critical, waveform types may remain untested.

Conversely, an artificial signal is noise-free and (in theory) has well-known properties. Conventional *phantom* ECG generators exist in the commercial domain which provide a noise-free wide range of lead configurations, heart rates, and arrhythmias. Unfortunately the details of the hardware used to generate these artificial signals are not available and so one can never know what the *ideal* input signal is, and what the clinical parameters in the signal are exactly. Another alternative is to generate the input signal by using an open-source algorithm (such as [56, 57]) which has completely known signal qualities, with markers for each clinical parameter. By varying the model over all possible heart rates, leads, and rhythms, and measuring the difference in all the clinical parameters, it is possible to rapidly determine under what circumstances the acquisition hardware causes significant distortions in the clinical parameters measured from the ECG. Of course, this method assumes that hardware to generate such as signal (with no significant distortions) already exists.

By far the most important step in the process of acquiring ECG is to ensure the safety of the subject being recorded. The standards that govern this evolve over time and differ from region to region, so no attempt is made in this chapter to give a definitive list of steps, and it is up to the reader to ensure that these steps are adhered to. At the time of this writing, the current international parent standard that addresses the many safety risks associated with electrical medical equipment (such as fire, mechanical hazards, and electric shock) is the International Electrotechnical Commission (IEC) Standard IEC 60601-1. This standard

also forms the basis for standards in many other countries including UL 60601-1 for the United States, CAN/CSA C22.2 No. 601.1 for Canada, and EN 60601-1 for the European Union.

However, the common issues that arise in testing electrical circuits that are connected to living subjects tend to be centered around how energy can be transmitted from or absorbed into the device. The ECG acquisition system not only has to be of no significant danger to the subject for which it is intended, but it must also not interfere with any other devices either directly or through radio frequency (RF) energy. Therefore, each device fabricated must be tested (and documented) for:

- *Isolation:* Power transfer must be limited between the nonisolated and isolated parts of the circuit (both through the DC-to-DC converters and opto-isolators).
- *Leakage currents:* The human body has a finite resistance (or rather reactance) and therefore conducts (and stores) electricity. Any powered device that is physically connected to the body (or comes within a certain physical range) can lead to the conduction of electricity from the device to the body.
- *RF emissions:* There are strict upper limits of the RF energy that a device may emit (within individual frequency bands) so that it does not interfere with other electronic devices in close proximity.
- *RF shielding*: Similarly, there are strict lower limits on the amount of RF energy that a device must be shielded against. That is, one must test a device to determine that all its modes of operation are unaffected when bombarded with RF energy across a wide frequency spectrum.
- *Surge protection:* In some environments, massive electrical surges are possible, such as in hospital, when a patient is defibrillated. If the equipment is to be used in such environments, it must be capable of returning to a normal mode of operation within a few seconds (depending on the device's exact function).

The exact acceptable limits often depend on a device's classification (which usually depends on its intended use, intended environment, power source, and electronic configuration). Such testing and adherence to regulations are particularly important when the device is to be used in clinical (or aviation) environments. Furthermore, the rapid progress of RF technology and the subsequent evolution in RF shielding requirements, indicates that a forward-thinking policy should be adopted when designing ECG acquisition systems (particularly for ambulatory or uncontrolled environments). Even in 1998, the IEEE Committee on Man and Radiation (COMAR)[17] [58] released a statement expressing concern about the growing number of RF emitting devices becoming available and what this would mean for medical device safety. COMAR recommended that RF interference-prone medical devices should be reevaluated and redesigned to to avoid serious safety-related RF interference problems. Of particular concern is the growing use of cellular phone technology. For a more detailed discussion of these issues and the latest IEEE standards information, see [58–63].

17. A group of experts on health and safety issues related to electromagnetic fields.

2.6 Summary

One of the most often overlooked issues when dealing with ECG analysis, is the path of the recorded signal between the sensor and the signal processing algorithm, and hence any possible biases the collection and storage methods may have caused in the subsequent analysis. These include the activity of the patient, the resolution and quality of the ECG, the lack of sufficient information (either from too few leads, or too few related signals such as blood pressure or activity annotations), and the selection of the population itself. Furthermore, the safe and secure storage of the ECG in a format that is easily read and annotated leads to an efficient and verifiable analysis.

In this chapter the main steps for designing and implementing an ECG acquisition system have been described with attention to the possible sources of error, particularly from signal acquisition, transmission, and storage. It is hoped that these discussions will not only provide the reader with sufficient background to design their own ECG collection system, but will also provide food for thought during the analysis stage. Being able to identify systematic anomalies in signals, that appear to have a physiological origin, is of great importance. Without experience or knowledge of the hardware used to acquire the ECG, it is often difficult, and sometimes impossible, to make this distinction.

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