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Implantable microelectronic devices

Christos Strydis

CE-MS-2005-06

Abstract

In recent years, biomedical engineering has seen phenomenal technological achievements. A particular subfield - biomedical, microelectronic implants - has emerged and, in time, gained much momentum. Starting with the implantable pacemaker some 50 years ago, such devices have been increasingly investigated over the last two decades, resulting in a plethora of actual systems of diverse capabilities and for various biomedical applications. However, the special nature of the implant application environment, i.e. the inside of the human body, poses many stringent design constraints, the two most important being low power consumption and small implant size. These have traditionally limited the design space of implant researchers and developers. Nonetheless, over the last few years, phenomenal advances in microelectronic technology, featuring ultra-low-power transistors of miniature size, have somewhat relaxed these two constraints, and have redefined what is "feasible" and what is not in implant design. Thus, new design approaches can now be investigated for developing new generations of powerful, multi-featured, tiny implants. To this end, a clear view of the current state of the art must, first, be acquired. By studying existing implementations and design choices, any deficiencies or overlooked issues as well as potentials or hidden trends can be successfully identified. The microelectronic technology being the vehicle, such an (unprecedented) study will be the basis for any future implementations. Motivated by the above observations, in this thesis we assume two tasks. Firstly, we perform a broad and scrutinous survey of existing implantable systems over a period of, approximately, 20 years. In this survey we collect, organize, at times clarify and, finally, report information for each studied system. As a second task and based on the findings of the survey, an exhaustive classification of the studied systems is presented and complemented with an in-depth annotation of the findings. Observations are made and general conclusions are drawn.

Implantable microelectronic devices
A comprehensive study

THESIS

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in

COMPUTER ENGINEERING

by

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In recent years, biomedical engineering has seen phenomenal technological achievements. A particular subfield - biomedical, microelectronic implants - has emerged and, in time, gained much momentum. Starting with the implantable pacemaker some 50 years ago, such devices have been increasingly investigated over the last two decades, resulting in a plethora of actual systems of diverse capabilities and for various biomedical applications. However, the special nature of the implant application environment, i.e. the inside of the human body, poses many stringent design constraints, the two most important being low power consumption and small implant size. These have traditionally limited the design space of implant researchers and developers. Nonetheless, over the last few years, phenomenal advances in microelectronic technology, featuring ultra-low-power transistors of miniature size, have somewhat relaxed these two constraints, and have redefined what is "feasible" and what is not in implant design. Thus, new design approaches can now be investigated for developing new generations of powerful, multi-featured, tiny implants. To this end, a clear view of the current state of the art must, first, be acquired. By studying existing implementations and design choices, any deficiencies or overlooked issues as well as potentials or hidden trends can be successfully identified. The microelectronic technology being the vehicle, such an (unprecedented) study will be the basis for any future implementations. Motivated by the above observations, in this thesis we assume two tasks. Firstly, we perform a broad and scrutinous survey of existing implantable systems over a period of, approximately, 20 years. In this survey we collect, organize, at times clarify and, finally, report information for each studied system. As a second task and based on the findings of the survey, an exhaustive classification of the studied systems is presented and complemented with an in-depth annotation of the findings. Observations are made and general conclusions are drawn.

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Dedicated to the ones who, irrationally enough, never gave up on me...

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Christos Strydis
Delft, The Netherlands
July 21, 2005

1 Introduction

1.1 Historical background

In its broadest sense, biomedical engineering has been around for centuries. Prosthetic body parts such as wooden limbs and reeds for looking and listening inside the human body are proved to have been used by ancient Egyptians as early as 3,000 years B.C.. In a stricter sense, biomedical engineering as we know it today, spans now more than 50 years of life. While in its infancy it has indistinguishably relied on and utilized more traditional disciplines such as biology and physics, it has now become its own, self-defined and outstanding discipline.

Rapid and astounding technological achievements have been presented thusfar with highlights in laboratory instrumentation, medical imaging, pacemakers, artificial limbs and computer analysis of the human genome, to name a few [48]. A field that has had a major boost in the last 15 to 20 years - and also the topic of this document - is *biomedical, microelectronic implants*. Perhaps the most widely known such device is the fully implantable pacemaker which was developed in 1958 and 1959 (of course, not microelectronic at the time) by Wilson Greatbatch and William M. Chardack. It has been the first device to be implanted successfully into the human body and to operate seamlessly for long periods of time - modern pacemakers feature an in-body lifetime of a decade or longer. It has, also, acted as a catalyst on the general public closed-mindedness against biomedical implants. Indicative of the penetration and significance of biomedical implants in health care these days is the number of people who have pacemakers worldwide: 4.3 million with at least 1.8 in the USA (as of May 2005).

Ever since the pacemaker, a plethora of other biomedical implants has also been proposed and designed for solving various medical problems and improving health care. However, many and great advances in micromachining technology [46] and in CMOS microelectronics have taken place of late and still keep making rapid progress. Such technologies have radically redefined the field of biomedical, microelectronic implants by providing an excellent substrate for the development and implementation of new generations of implantable devices. These devices can now feature advanced settings and functionalities while preserving miniature size and sub-milliwatt power consumption.

Many medical problems are being addressed by these devices, for instance functional electrical stimulation of patients for paralyzed-limb control, for suppression of chronic pain, for partial restoration of eye sight, for bladder control etc. Also, measurement of physiological parameters such as temperature, pH and blood glucose concentration

is achieved or monitoring of in-body strains caused by installed prosthetic limbs and so many more. A common characteristic in many of these implementations is the ability of the implant to percutaneously accept commands from an external host system (e.g. computer, hand-held device) and/or to transmit physiological data outwards, as measured from inside the body. This information exchange is often achieved through a wireless interface established between transmission/reception antennas of the involved parts. Acquisition of physiological data on the part of the implants is usually achieved through appropriate *sensors* whereas intervention to the human body (such as insulin administration or the above discussed electrical stimulation) is effectuated through *actuators*.

1.2 Thesis stimulus

The impressive improvements of biomedical implants, supported by the rapid achievements in microtechnology, have untied the researchers' hands who gave way to a wide range of design approaches and implementation techniques. This plurality of methods has been the incentive for the current thesis, which has a twofold purpose. Firstly, we investigate a large number of microelectronic implants in an attempt to present a clear picture of the past and present state of things in the field. To do so, more than 60 implant cases have been studied and included in the survey. In it we have collected, organized, at times clarified and, finally, reported information for each studied system in a carefully structured manner. While various aspects of the presented implantable systems are being reported, in this study we are particularly interested in the processing and/or controlling architecture of implantable components themselves. The reason is that architecture is the part to benefit greatly from the advances in microtechnology and, due to this fact, also the part that much innovation is seen. Conversely, device packaging (and other mechanical features) is not elaborated much in this document. This does not mean that packaging is not important. Rather, packaging is a hot topic on its own for biomedical implants these days since it is one of the key elements for chronic implantation of devices (another one is power-source longevity). However, it pertains to other fields of study, like for instance material science, and therefore falls outside the scope of this study.

This document would be incomplete without an accompanying classification and study of the survey findings. This is the second goal of our work. Therefore, an all-out classification of the gathered information is performed. A large number of features of the implantable systems is lined up enabling correlations and comparisons between the various implementations. By observing the data, underlying trends of the last 15 to 20 years are identified, implant capabilities and deficiencies are pinpointed and recommendations are made for future implementations. To the best of the authors' knowledge, no similar study has been attempted before on the field of microelectronic implants.

1.3 Thesis organization

In chapter 2 of this document, a large number of microelectronic implants is presented. Systems targeted for varied applications have been picked to give a broad view of the field. For each of them, various design aspects are discussed. In the end of the chapter, some additional cases are included which are not (fully) implantable systems, yet present interesting developments.

Chapter 3 makes a classification of the described systems, based on an extensive set of attributes. The findings are commented on and underlying trends are identified.

Finally, chapter 4 summarizes the work performed in the previous chapters and extracts general conclusions and observations. The contributions of this study are reported.

Investigation of microelectronic implants

2

2.1 Introduction

This chapter is involved with the task of presenting an extensive subset of currently existing biomedical, microelectronic implants. An attempt has been made to make this subset as representative as possible by reporting a wide range of application scenarios as well as design approaches proposed by various researchers. In the following text, more than 60 systems are discussed in detail. Furthermore, some special cases are also discussed in the end of the chapter. Information is given about their composition, technical characteristics, originality and, of course, functional purpose. This investigation serves two goals; firstly, it will allow the reader to acquire a good sense of the past and present implementations in the field. Secondly, it will form the backbone for the next chapter, where an involved classification and comparison of the discussed systems takes place.

Very early in the survey it was made clear that the majority of the proposed implantable systems shares common attributes in their organization. More specifically, such systems typically consist of an implanted (in-vivo) module and one or more external (ex-vivo) host modules that control and/or audit the internal one by means of a communication (e.g. wireless) link. This observation along with the desire to make a uniform, well-structured approach has led us to segment the study of each reported system into several subcategories, as follows:

i. **Application scenario**: it pertains to the medical usage of the system, i.e. what the implant is aimed at.

ii. **General overview**: it gives a description of the functional building blocks of the whole system and their roles. This subcategory helps to gain perspective and understand the interconnection between all involved parts.

iii. **Implanted part**: it delineates the structure of the implant itself, its internal components and technical characteristics.

iv. **External part**: it, respectively, gives the specifics of the external part(s) of the system, if any.

v. **Communication scheme**: it reports the type of communication between the internal and external parts. Supported bit rates, featured protocols, modulation and data encoding techniques are some of the information given.

vi. **Electromechanical specifications**: it includes general information regarding the discussed system such as power consumption, physical size, packaging, implementation technology and other.

vii. **Miscellaneous issues**: this part is dedicated to reporting original contributions and unique features of a system - features that are not met in other designs. Additionally, this field may contain all other pieces of information that do not belong to any of the previous subcategories, e.g. experimental results, future work on a system and other.

Even though the investigation covers sufficiently all above subcategories. Yet, as mentioned in chapter 1, special emphasis is placed on the implant processing/controlling architecture. Issues such as the fabrication process or micromachining techniques of the utilized sensors and actuators or of the implant itself, although briefly mentioned, are not described in detail, since they are not the primary consideration of this document.

2.2 Cases of medical, implantable, microelectronic devices

In this section, the investigated systems are discussed. It should be noted, however, that many authors fail to provide (some or any) information on one or more of the above subcategories. The policy followed in this report is to include only explicitly stated information with the exception of trivial calculations on power consumption (e.g. from mentioned voltage and current levels of a device) for reasons of completeness. Nonetheless, the reader is encouraged to refer to the full paper of a described system for a more involved discussion. Needless to say, the text included in the following subsections strictly expresses the views and opinions of the authors of the proposed systems.

2.2.1 A completely programmable and very flexible implantable pain controller (Mouïne et al., 2000) [44]

Application scenario
Normally, the purpose of a pain signal is to act as a warning that protects the body from potential harm. When the cause of the pain has been remedied and no additional injury or healing is occurring, at this point, pain no longer serves the purpose of warning, so it becomes the disease that needs treatment. Chronic pain can be very stubborn and disabling and may not respond to drugs and other standard therapies. One available therapy offering possible hope to a subset of chronic pain patients is spinal-cord stimulation (SCS). This therapy consists of electrical impulses triggering selected nerve fibers along the spinal cord. The stimulation of these nerve fibers inhibits pain messages from being transmitted to the brain.

The proposed system is a passive, programmable, implantable stimulator device for administering nerve stimulation to chronic-pain patients. External modules wirelessly transmit stimulation commands and parameters to the implant.

General overview
The system comprises of two external-controller parts (a desktop computer and a small patient unit) and the internal microstimulator device. Communication between the exterior and the interior of the body is achieved through an inductive telemetry link (see Fig.2.1).

Implanted part
The microstimulator is a mixed-signal ASIC which can be programmed to deliver various biphasic stimulation patterns to the patient. The, above depicted, dedicated microprocessor (mP) chip is a finite-state machine (FSM) capable of providing random stimuli, ramping stimuli, combined stimuli and control of nerve fatigue and excitation to drive maximally four stimulating electrodes. The adjustable signal parameters are waveform shape, duration, amplitude, frequency, relaxing time (between the anodic and cathodic phase of the pulse), randomization and synchronization. Randomization is considered an important feature since it prevents the stimulated nerve(s) from habituating to specific stimulation patterns, effectively rendering the implant useless. Current pulses rather than voltage stimuli are delivered so as to be independent of the adjacent tissue impedance (i.e. load). The microprocessor can execute microcommands which it wirelessly receives from the external (host) computer. With these com-

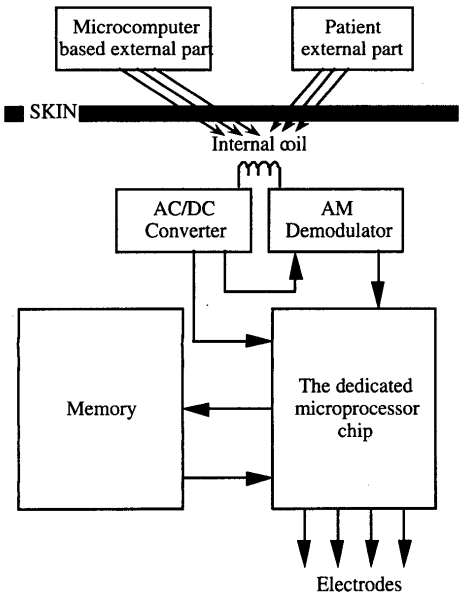

Figure 2.1: *Pain stimulator system block diagram.*

mands it can read inputted data and create and administer the desired therapy program. The transmitted commands are 16-bit long and can contain information such as a pulse polarity bit, a 3-bit current magnitude, a 4-bit electrode address or a 9-bit time-delay argument.

External part
The external host computer is running a specific application software which enables a treating therapist to program the microstimulator with stimulation parameters best tailored for the patient needs. The second small external unit is meant for use by the patient himself. Once the appropriate data have been loaded on the device by the therapist, the patient can start and stop the stimulation at his convenience.

Communication scheme
Power for the implant as well as data are transmitted from the host through an inductive RF link on a 20-MHz carrier. Data are AM-modulated, Manchester-coded so as to include also clock synchronization (reference) information for the implant and are serially transmitted. The received RF signal is picked up by an internal coil; an AC/DC-voltage converter is used to rectify the carrier signal for powering the circuit and an AM demodulator for isolating the AM envelope which contains the command words for the mP.

Electromechanical specifications
For the implanted system, a full-custom mixed-signal ASIC has been designed and implemented in BiCMOS 0.8 μm technology. The chip has been mounted on a thick-film hybrid circuit together with the analog circuitry for power/data transmission and a memory chip. No power figures are reported.

2.2.2 A microcontroller-based implantable telemetry system for sympathetic nerve activity and ECG measurement (Enokawa et al., 1997) [19]

Application scenario

Enokawa et al. have proposed an implantable, passive-telemetry system for renal sympathetic nerve activity (RSNA) and electro-cardiogram (ECG) monitoring. Such signals are indicative of normal function of the human body and their monitoring gives valuable information about any underlying or potential problems.

General overview

The system consists of two external parts and one internal module - the implantable device. The external parts are a desktop computer and a backpack unit. Communication among the above components is hierarchical in the sense that the computer communicates with the backpack and the backpack with the implant (see Fig.2.2).

Implanted part

The implantable device is a PCB-mounted chipset which measures renal nerve signals (RNS) and ECG signals through electrodes. These signals are amplified on the implant by two low-power instrumentation amplifiers and are, then, fed into the controlling module of the implant. That is a low-power, $8-bit$ CMOS microcontroller (mC, PIC16C71) which receives the amplified signals into two independent, on-chip (8-bit) ADC converters and at a sampling frequency of 2 kHz[1]. The mC is capable of adjusting the gain of the above amplifiers by receiving commands from the external computer (through the backpack). The digital data generated by the ADCs are incorporated in a 21-bit stream that the mC transmits serially to the computer (through the backpack).

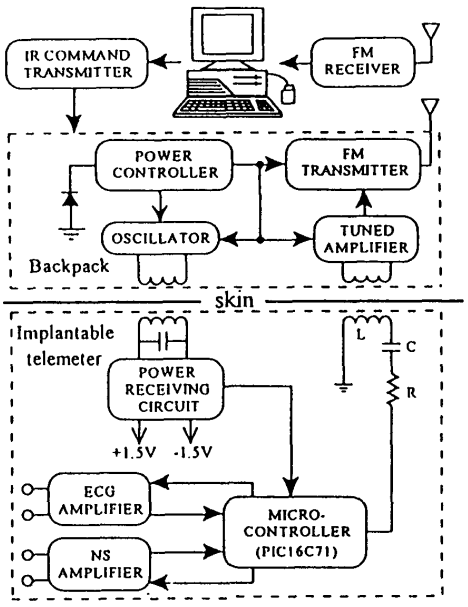

Figure 2.2: *Computer - backpack - implant setup.*

External part

The computer is supervising the whole operation cycle of the implantable system by transmitting implant power-on/power-off or amplifier-gain commands to the backpack. The backpack includes a power controller, an oscillator, a tuned amplifier and an FM transmitter. When receiving a power-on command from the computer, the power controller turns on the whole backpack. Then, the backpack transmits power and data (amplifier-gain commands) over an inductive coil to the implant.

[1]since the frequency bandwidths for ECG and RNS are $0.5-200\ Hz$ and $50-1000\ Hz$, respectively.

Communication scheme
In this design, different means of transmitting power/data are being used. The desktop computer transmits commands to the backpack over an IR beam. The backpack receives the commands, powers up (or down) and forwards the computer commands to the implant over an inductive link. The oscillator used generates 9 V_{P-P} sinusoidal waves at 200 kHz to drive a primary coil. The waves are modulated by 144 bps on-off keying of the commands. The receiving end uses a full-wave rectifier, a voltage regulator and a DC-DC converter which supplies symmetric voltage of 1.5 V to the implant circuitry. The implant, in turn, applies its synthesized 21-bit pulse train to a passive RLC resonant circuit (resonant frequency set at 8 MHz)which is received by a tuned amplifier in the backpack. This technique is commonly known as impedance-reflection modulation. The tuned amplifier, finally, forwards the data to the computer with an FM transmitter.

Electromechanical specifications
The implantable device is constructed on a 40 mm $\times$ 35 mm PCB, has a total volume of 15 cm^3 and weighs 46 g. Implant power consumption is not discussed. Still, given the fact that a PIC16C71 is utilized inside the implant, a minimum consumption of 10 mW (2 mA @ 5 V) for an operating frequency of 4 MHz is anticipated. However, this figure is probably unrealistic since on-chip ADCs are active and the rest of the implant circuitry (e.g. passive-RLC circuit, gain amplifiers etc.) present also consumes power. Thus, the power consumption should be substantially higher than 10 mW.

2.2.3 A portable microsystem-based telemetric pressure and temperature measurement unit (Flick et al., 2000) [23]

Application scenario
The measurement of intracorporal pressure is very crucial especially to a small group of patients in the neurosurgical field. The possibility that pressure and temperature can be measured in all areas of the intensive care unit with mobility would be a real benefit for these patients. There are a number of brain diseases with increased intracranial pressure (ICP), such as hemorrhaging, tumors, abscesses and parasites, creating a need to measure ICP. On these grounds, the authors have developed a passive, telemetric pressure- and temperature-measurement CMOS system for intracranial implantation.

General overview
The proposed system is termed as a "two-cut system" since it consists of three distinct parts: the intracorporal unit, a mobile unit (first cut) that communicates with the implant over an RF inductive link and displays measured data, and a stationary unit (second cut) which communicates with the mobile one and processes measurements (see Fig.2.3). Also, the external mobile unit is presumably charged with the task of inducing power to the passive implant through the RF link.

Implanted part
The implant consists of a CMOS-compatible pressure and temperature sensor with PWM output. This is fed to an ASIC for storing and modulating sensor readouts and for transmitting them externally. The sensor is based on a piezocapacitive rather than a piezoresistive principle for achieving lower power consumption and higher precision. The telemetry ASIC modulates the PWM data on a $4-MHz$ carrier frequency supplied by the external transmitter. Presumably, impedance-reflection modulation is used and PWM data are transferred wirelessly to the outside over an on-chip coil.

External part
The implant communicates its data to an external portable unit which samples and records pressure and temperature data. To this end, a PIC16C61 microcontroller (mC) is used to convert the PWM train to a serial bit stream. A second sensor

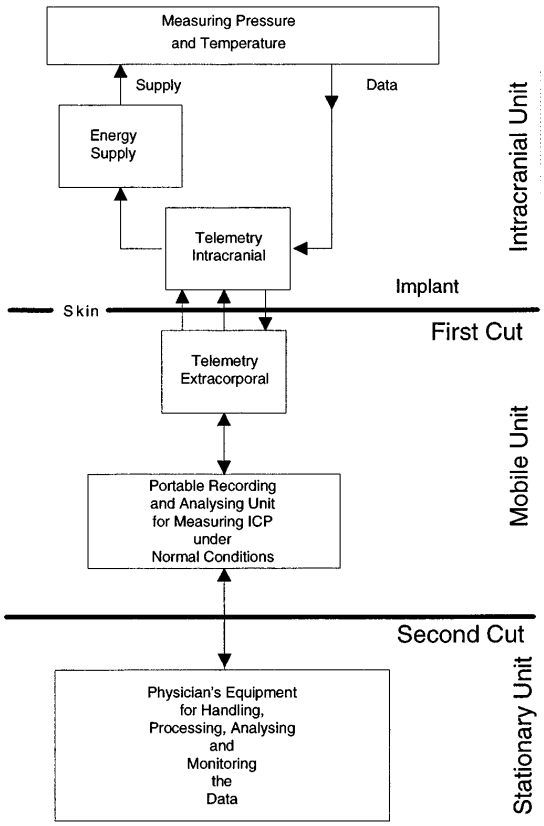

Figure 2.3: *Block diagram of two-cut pressure and temperature measuring system.*

(similar to the intracorporal one) is also connected to the controller to measure the atmospheric pressure and temperature since atmospherics are known to change the intracorporal pressure (ICP). The PIC mC is, in turn, connected via an RS-232 link to a second mC (Intel 80C517) which collects the data in a PCMCIA card and displays them on an LCD. The mobile unit can selectively perform some basic pattern recognition on the acquired data looking for specific events to trigger the attention of a supervising technician. The measured data (along with any triggered events, if any) are transferred to a stationary computer for further (offline) processing. Apart from the temperature, such data include the ICP signal which consists mainly of three signals: the basic part (plateau), the respiratory and the cardiac component. The basic part has a frequency BW of 0.09 Hz and includes the so-called *Lundberg waves* (A, B, C, D and E). The respiratory part has a frequency BW of 0.21 Hz and allows screening hyper- and hypo-ventilations of a patient. Finally, the cardiac part has a frequency BW of about 1 Hz and can be used to extract ECG data. Even though it is desirable to measure a whole signal instead of single values of the above components, however, continuous sampling of those data at a high frequency is not possible due to power-consumption limitations of the implant. Therefore, the system has been set to collect 50 samples every 15 sec at a sampling frequency of 40 Hz.

Communication scheme
As discussed above, communication between the implant and the portable unit occurs wirelessly over an RF link. The implant is passive and, thus, is probably powered by the same RF carrier signal which stimulates its sensors to acquire data and transmit them externally (by the impedance-reflection technique). Communication of the mobile unit with the second mC (Intel) is trivially achieved over an RS-232 standard connection.

Electromechanical specifications
The implanted unit is in fact a cost-effective polyimide flextape with size $6\ mm \times 28\ mm \times 2\ mm$ onto which the sensor is mounted and the telemetric ASIC is developed. Coil-on-chip technology is utilized and a coil is etched on the ASIC effectively allowing for induction coupling between the implant and the mobile unit (i.e. incoming power and outgoing data transfer). The overall power consumption is 5 mW (4 mW attributed to the sensor and 1 mW to the ASIC).

2.2.4 Advanced hybrid integrated low-power telemetric pressure monitoring system for biomedical applications (Eggers et al., 2000) [18]

Application scenario
Eggers et al. are also proposing an implantable, ICP measurement system. A telemetry-powered implantable system consisting of an absolute-pressure sensor and two low-power ASICs for pressure read-out and telemetric data/power transmission is presented. Emphasis is put on the fabrication choices for the system; a flip-chip mounting and assembly technology has been used leading to a hybrid integration (as opposed to a monolithic implementation).

General overview
The telemetric pressure measurement system has a standard setup. It comprises the internal unit, an external telemetry unit (for data and power transfer to the implant) and a computer for storing and analyzing the measured data (see Fig.2.4).

Implanted part
The sensor used in the implant is a micromachined capacitive one. The read-out circuit is a low-power, differential switched-capacitor (SC)-relaxation oscillator with 10-bit resolution and quasi-digital PWM output. This output is fed to the second, telemetry ASIC for transmission over a hybrid-integrated micro-coil. The authors stress that a coil-on-chip technology (as previously encountered) is avoided so as to minimize implant area. The read-out circuit is capable of sampling speeds up to 100 samples/sec. The 10-bit resolution of the (pressure) data implies a 0.1% (= 100 Pa = 1 $mbar$) measurement accuracy which is considered adequate for a variety of medical research and diagnosis purposes. The telemetry ASIC provides the read-out ASIC with a $125 - kHz$ clock at 3.5 V power supply. This chip performs data reduction for the PWM signal as well as encoding and modulation.

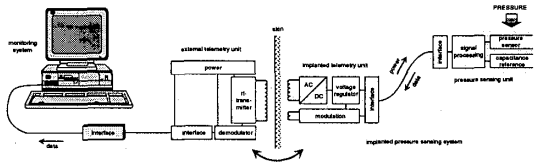

Figure 2.4: *Setup of telemetric, pressure-measuring system.*

External part
No explicit mention of an external supervising system is provided.

Communication scheme
Communication of the implant with the outside environment is provided through a passive RF inductive link. The external host provides the implant with power by transmitting a carrier with frequency 4 MHz which the telemetry ASIC rectifies and stabilizes for the sensor to operate smoothly. Conversely, data are transmitted outside by passive-absorption modulation (also known as impedance-reflection modulation).

Electromechanical specifications
The emphasis in this paper is on the fabrication approach taken. The authors state that monolithic implementations of sensory circuits are only justified in high-volume markets as the automotive area (and not the biomedical area, as sales have shown so far). Thus, a monolithic, mixed-signal CMOS/BiCMOS chip implementation of the above implant would benefit size but would greatly increase cost. Older and simpler fabrication techniques can be used with multi-chip implementations. To alleviate the problem in size, a flip-chip mounting and assembling technology has been used and a hybrid system is fabricated. The read-out interface ASIC is developed in $0.7-\mu m$ CMOS process. Both ASICs are processed on one side of the silicon substrate which is a flex-foil carrier. Power consumption is primarily affected by the read-out ASIC which is reported to require $350\mu W$.

2.2.5 An implantable analyzer of bio-impedance dynamics - mixed signal approach (Min et al., 2001) [43, 42]

Application scenario
The electrical bio-impedance (EBI) contains much information about the physiological performance of living tissue. Devices that monitor the EBI can follow the functionality of transplanted tissue or organs and warn a physician of alarming situations such as tissue rejection, hypoxia, ischemia, swelling etc.. This method has recently found practical use in cardiac pacemaker technology. The authors propose an implantable analyzer of bio-impedance signals. The analyzer is a front-end, mixed-signal and low-power ASIC which is capable of measuring both the real and the imaginary part of the (bio)impedance at several frequencies so as to discover malignant tissue changes. By measuring both parts, more reliable diagnostic results are achieved according to the authors.

General overview
The EBI contains "bio-modulated" information about breathing and heart beating. In order to discriminate both these components together with separation of their real and imaginary parts, specially designed, synchronous demodulation micro-circuits are required. The authors propose an on-chip implementation of a two-frequency dynamical EBI analyzer, covering 1 to 8 kHz within a lower-frequency band, and 1 to 128 kHz within a higher-frequency band. Figure 2.5 conceptually presents the setup for one of the two frequencies in an IC; for the second frequency a similar (duplicated) circuit setup is required. It should be noted that simultaneous operation at two different frequencies is performed properly if the

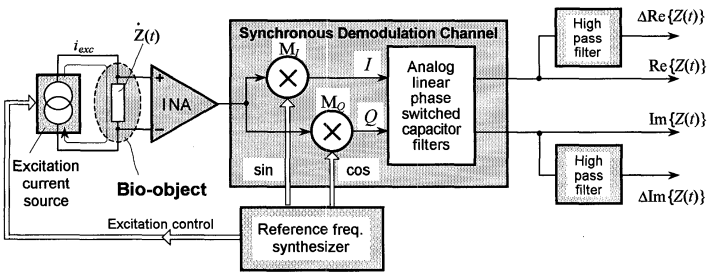

Figure 2.5: *Block diagram of the EBI analyzer (single frequency).*

higher-frequency channel operates at a frequency equal to the frequency of some even harmonic of the lower frequency channel. This is taken care of by the authors by setting the minimum distance between coinciding frequencies to 47 times as far, thus introducing a negligible error (due to coinciding harmonics).

Implanted part
Each segment of physiological tissue presents a specific (bio)impedance value which is indicative of the condition of the tissue. Based on this fact, the functionality of the analyzer concisely is as follows: a current source is connected in series to the tissue under measurement. This current source is a special DAC which is controllable by the digital signal of the reference frequency synthesizer. In this way, a closed circuit is formed and an excitation current is built up which generates a voltage proportional to the complex bio-impedance $Z(t)$ of the tissue. Then, the analog signal is amplified and multiplied by discrete sine and cosine reference signals. The in-phase (I) and quadrature (Q) output signals now contain information about the real and imaginary part of $Z(t)$. Subsequently, the low-pass, linear-phase SC analog filter is used to extract distortion-free signals of the basic component of $Z(t)$ and also variations $\Delta Z(t)$ present due to respiration and cardiac function. The effective respiratory band is up to 1 Hz and the cardiac one is from 1 to 25 Hz. In order to separate them from the rest of the composite bio-impedance signal, typical high-order, non-recursive digital FIR filters operating at a a sampling frequency of, say, 100 Hz can be used. Nonetheless, this solution is deemed very resource-demanding for the case of implantable devices since it will bind a significant part of the built-in mP. The authors propose a more efficient solution, as follows: the signal is passed through a $25 - Hz$ prefilter which allows for reducing the sampling frequency to 50 Hz for further processing. Furthermore, different sampling rates can be used for the two components since they have different frequency regions. Also, the two main filters can be made adaptive to the actual (rough) data (beat rate and heart rate) from the impedance signal $Z(t)$. It should be noted that the utilized filters are digital in nature. The authors have anticipated that, after this point in signal processing, any further manipulation of the handled physiological signals will have so sophisticated needs that digital processing will give far better results than analog processing.

External part
No external system has been specified for the implantable analyzer save for the testing environment used for validating chip functional behavior. Hardware-wise, an EBI phantom has been used to this end which is a specially designed device for converting an analog control signal into the corresponding variation in impedance. LabView control software has also been used and custom developed for testing the chips.

Communication scheme
No information is given on the communication means between the implanted chip and an external control or monitoring system.

Electromechanical specifications
The whole chip is set to a clock frequency of 4 MHz. 2 μm CMOS technology has been

used for the chip, which is commonly used in precision analog ASICs. The technology includes continuous-mode, discrete-time and digital circuits. Nevertheless, it should be noted that at the time of the paper publication, the digital filters had not been included to the chip design yet. The power consumption for the circuit is reported to be 13.75 μW (55 μA @ 2.5 V). A prior version of the ASIC is given in [42] with almost double power-consumption characteristics.

2.2.6 Development of a biotelemetric heart valve monitor using a 2.45 GHz transceiver, microcontroller, A/D converter, and sensor gain amplifiers (Sears et al., 1999) [61]

Application scenario
In the specific case of implanting an artificial heart valve, the physician is particularly interested in measuring cardiac output (e.g. blood pressure). To this end, many methods exist such as thermodilution, electromagnetic probes and ultrasonic Doppler probes, but they are all invasive and somewhat inaccurate ones. The authors are relying on a new method which calculates beat-to-beat aortic flow from differential pressure measurement. An implantable monitoring system is proposed which can be attached to a cardiac valve to acquire data and transmit them wirelessly to an (external) computer for display and further processing.

General overview
The (not yet implemented) system shall consist of the implant itself and an external host computer. Over an RF inductive link, the computer issues commands to the implant and it - in turn - transmits telemetric cardiac-valve pressure data back.

Implanted part
A large-scale (i.e. not implantable) circuit was developed to model such an implantable system for proof of concept. The conceived system consists of two (currently unimplemented) micromachined pressure transducers which can be attached one at each side the artificial heart valve to measure pressure differentials and of read-out microelectronics for data acquisition. It also contains two low-power instrumentation amplifiers (AD620) for boosting the signal level of the two channels (i.e. the two transducers) and a mC (PIC16C76) for 8-bit analog-to-digital conversion of the amplified channels. Finally, a 2.45-GHz transceiver chip (MicroStamp Engine) is used for RF-transmission of measured data to the computer. Also, the computer can transmit manipulating commands to the implant but their structure and purpose are not discussed in this paper. For command and data transmission, patch antennas have been used.

External part
In this version of the system, as supposed "external" host, a computer running custom software is being used. This software is developed for controlling the implant and consuming the data it emits. The RF link is set in the 2.45-GHz frequency and is the highest frequency cleared for biotelemetric use which is known to the authors.

Communication scheme
Communication is achieved over the RF link, on which the computer transmits commands and the "implantable" circuit replies with pressure readouts. According to [11], the MicroStamp chip receives commands by the external host with the direct-sequence spread-spectrum (DSSS) technique at an effective rate of 159 $kbps$. Yet, (data) transmission back to the computer is achieved by adding data to the host's unmodulated signal with differential-phase-shift-keying (DPSK) modulation. The effective data rate supported is 92 $kbits/sec$. Data words contain 13 bits, 8 for data and 5 for error-correction codes.

Electromechanical specifications
Since this is a rapid-system prototype of a proposed implantable device, no information is given on dimensions or packaging. Power consumption of the prototype is not discussed, too. However, should the same (miniature) components be used for synthesizing the implantable device itself, a lower bound for the power consumption can be estimated from the consumption of the PIC16C76 mC and the MicroStamp Engine which are respectively equal to 45 μW and 500 mW. It should be stressed out, though, that these figures may not be indicative of the final, implantable system, if the utilized components are changed with custom integrated or less power hungry ones.

Miscellaneous issues
The micromachined transducers are not yet implemented and, thus, the system has been tested with triangular-wave input signals with frequencies of 2 to 10 Hz instead. Error analysis of the system revealed an average error of 4.1% per waveform. This error appeared to increase with increasing waveform frequency and to decrease with increasing sampling rates.

2.2.7 Totally implantable real-time in vivo video telemetry monitoring system for implant biocompatibility studies (Beach et al., 2001) [8]

Application scenario

Implanting medical devices into living tissue causes tissue injury and, therefore, a body response. The tissue response to the trauma can be broadly viewed as a two-step process; the tissue *inflammation* and the actual *wound healing* consisting of regeneration, repair (fibrosis) and neovascularization (angiogenesis). However, the tissue response to an implant can greatly deteriorate or even nullify its function. It is, thus, crucial for the physicians to be able to monitor how the tissue surrounding the implant behaves.

Currently, the method for doing so is by histological examination of the tissue around the implant. Main disadvantages of this method are the need to sacrifice (at each time point) a big number of test animals for surgically removing the tissue, the labor-intensive nature of the technique and its inability to assess tissue reaction at specific sites at all times. In this context, the authors are proposing an implantable system which is capable of in vivo assessment of tissue response by providing real-time images of monitored sites.

General overview

The implantable system comprises a miniaturized camera, a TV video transmitter, a 4-LED illumination module and a 9-V battery. The TV video signal is telemetered out to a TV set or VHS video cassette recorder (VCR). Communication in this system is unilateral in the sense that the implant only transmits data outside but does not receive any power or data components. A block diagram of the overall system can be seen in Fig.2.6.

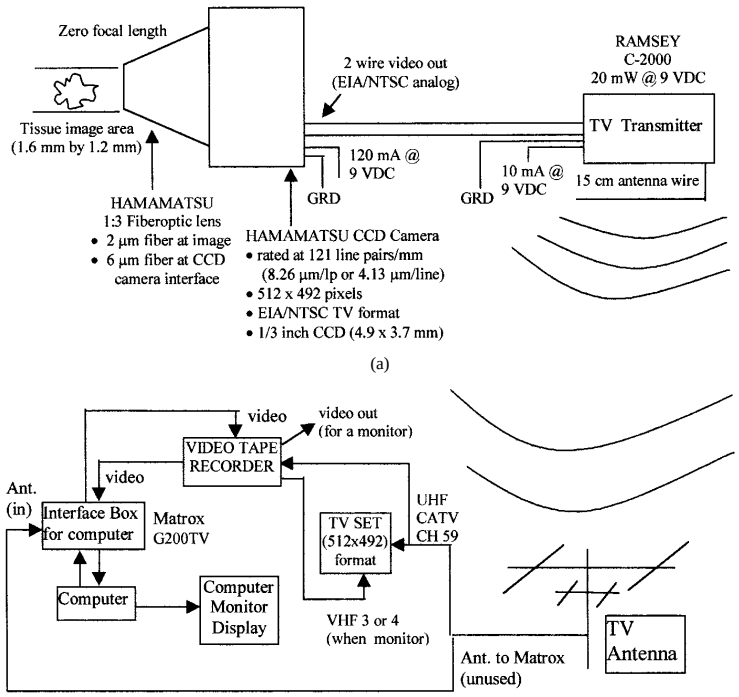

Figure 2.6: *Block diagram of in vivo video telemetry system.*

Implanted part

The most important component of the implant is the fiber-optic, lens-based CCD camera (Hamamatsu) of miniature dimensions. The camera has been picked based on its dimensions, resolution and magnification. The resolution of the camera is rated at 121 lp/mm. The camera lens is a 1:3 tapered lens and the fiber diameter in the input

side is 2 μm, therefore expanding to 6 μm at the output (CCD) side (i.e. optical zoom: 3×). The effective image size is 1.6 mm × 1.2 mm in the input (and triple in the CCD side) and is mapped to 512 × 492 pixels. This mapping (along with the optical 3× zoom) results in an actual, total magnification of 70× to 200×, depending on display or printout media dimensions. The camera has a zero-focal-length lens meaning that the lens has to actually come in physical contact with the monitored tissue site (for ideal object focus).

Illumination of the camera has been achieved by mounting 4 LEDs (Nichia pure white) in a module around the camera, providing white light. Operating at 20 mA and 3.6 V, each LED has a measured illumination of 986 lux. In the prototype built for this paper, 2 double-LED units have been used with an illumination of 3560 lux. The video camera output consists of two wires (EIA/NTSC format). This two-wire signal is connected to a miniature video transmitter (Ramsey) for transmission over a standard TV channel reception frequency. The unit operates at 10 mA and 9 V (and is rated at 20 mW of transmitted power).

External part
A short-length wire (150 mm) has been used as an antenna to transmit EIA/NTSC-compatible images. The receiving antenna is of standard VHF telescoping rabbit-ear type (since the desired frequency resides at the low end of the UHF band). As shown in Fig.2.6, the over-the-air transmitted signal can be captured by any available tuner for display or processing. In this case, a TV set and a VCR have been used. Through the video out of the VCR, the signal is further forwarded to a computer tuner/grabber card (Matrox) for post-processing of the recorded image sequence. JPEG compression has been applied to the video feed before storage. In the computer, full field of view of the implanted camera can be achieved and also image analysis methods are performed by using NIH software.

Communication scheme
The RF frequency utilized by the implanted transmitter is the CATV channel 59 UHF (@ 433.25 MHz). The authors have taken into account the effect of tissue absorbtion on the RF signal and found that for a typical 3-mm skin thickness, 92.41% of the initial power is preserved. This allows for an effective maximum reception distance of 5 to 10 meters away from the test subject.

Electromechanical specifications
The camera dimensions are: 32 mm × 32 mm × 26 mm and those of the transmitter: 17 mm × 17 mm × 7 mm. The illumination module and video camera are packaged within a protective plastic case of dimensions: 31 mm × 54 mm × 28 mm. It should be noted that at the time of the paper, the authors had not yet tested a fully-implantable system. The total power consumption is calculated to be 1080 mW (namely, 120 mA for the CCD, 10 mA for the transmitter and 40 mA for the 2 double-LED units, all at 9 V). A 9-V Lithium battery (Ultralife) providing 1200 mAh has been used. However, continuous operation would give about 7 hours of operation. Therefore, the authors

propose (but don't implement) a sampling circuit with an ON time of one minute per hour (1/60) effectively prolonging battery lifetime to about 17 days.

Miscellaneous issues
Directly extracted and telemetrically transmitted images show virtually no difference by visual inspection and by computer analysis, for all in vivo, ex vivo and in vitro measurements. Last but not least, the authors actively consider the issue of radiation interference with living tissue due to the RF signal. Based on established ANSI/IEEE Maximum Permissible Exposure (MPE) limits, they calculate the maximum tissue exposure index (in mW/cm^2) and find it slightly deviating from the MPE limit.

2.2.8 A 0.5mW passive telemetry IC for biomedical applications (Huang et al., 1998) [33]

Application scenario
Passive-telemetry medical devices consist of one or more sensors and other accompanying electrical circuitry for monitoring some specific physiological parameter of a living organism. Power for these parts is provided commonly through an RF link (usually in the ISM frequency band[2]) by some external base unit. Sensory data is, then, transmitted in the opposite direction; from the device to the external base unit. Nonetheless, the size constraints for such devices explicitly impose small dimensions for the implant coil which is used for coupling (usually there is no restriction for the external coil). This effectively results in the implant capturing only a small fraction of the radiated electromagnetic power, i.e. less than 1 mW. For this reason, the authors of this paper are proposing the design of an IC than can be interfaced to a number of different sensors while incorporating low-power components for data acquisition (from the sensor) and transmission so as to keep power consumption very low. Towards this end, the implanted unit is carefully designed for low power consumption both at system level and at circuit level. As a demo application, a magneto-resistive sensor bridge for blood-temperature measurement has been ported to the telemetry IC.

General overview
Focus in this paper is concentrated on the functionality and components of the passive-telemetry chip. An external host system capable of collecting the measured and telemetered data is assumed but is not delineated.

Implanted part
The block diagram of the passive-telemetry IC is depicted in Fig.2.7. It includes a low-noise, low-offset instrumentation amplifier, a low-pass notch filter and a 9-bit ADC. It also includes an on-chip clock generator, elements of an RF/DC converter, bandgap reference circuitry, a supply-voltage regulator, sensor control logic and data-modulation circuitry.

[2]Industrial-Scientific-Medical band

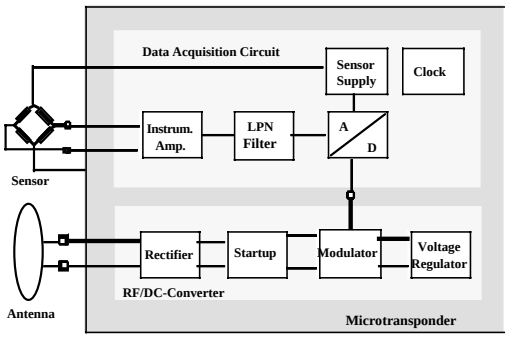

Figure 2.7: *Passive-telemetry IC block diagram.*

First off, continuous read-out of the sensor data would lead to prohibitive power requirements, therefore a sampled-data front-end is required for the IC. For this reason, the sensor output is fed into a low-noise, low-offset instrumentation amplifier of switched-capacitor nature to effectuate the data sampling. The signal bandwidth of physiological signals is about 30 Hz and the necessary sampling frequency should be less than 100 Hz. However, no special anti-aliasing filter is present before the data is amplified, so the clock frequency is set to 1 kHz to minimize aliasing of interfering signals and to ease the time-constant requirement of the oscillator. The SC amplifier characteristics are 26 dB gain, 45 μV offset, 39 dB maximum SNR and it consumes 30 μW (10 μA @ 3 V). To limit noise bandwidth and to remove interfering signals, a 2nd-order SC low-pass notch filter is implemented with a cut-off frequency at 35 Hz and notch frequency at 50 Hz. This component consumes 60 μW (20 μA @ 3 V).

Since the signal bandwidth and dynamic range are both low, a dual-slope, 9-bit ADC has been selected which is considered the most power-efficient implementation (due to the simplicity of the analog and digital parts). The ADC averages three consequent samples from the notch filter to generate a 9-bit value. Voltage regulators are usually designed to have as much current delivering capability as possible. However, current requirements for the specific IC are small, therefore the voltage regulator is built to consume as little power as possible. Finally, the oscillator circuit is of the relaxation type and has a nominal frequency of 100 kHz.

External part
Since this is the description of a general-purpose passive-telemetry IC for medical implants, no specific external system setup is described.

Communication scheme
For the specific implementation, the authors have selected the band of 27 MHz and a small coil for the RF power and data link of the implant. Since the available power is not sufficient for conventional radio transmission, *absorption modulation* is selected for data transmission. This modulation scheme is achieved by altering the reflection index of the implanted coil at the instants of data transmission by shorting the coil, effectively causing a glitch in the reflected waveform seen in the base unit. 9-bit quantities from the ADC are serially transmitted to the base unit at a rate of one bit per system clock cycle. The clock of the base unit is phase-locked to the clock of the implanted IC by means of a leading sync pulse per 9-bit quantity.

Electromechanical specifications
The IC is realized in 2 μm, 40 V BiCMOS technology, mainly to take advantage of the available $12-V$ Zener diodes as protection devices at the input of the voltage regulator. The die size is 4 $mm \times 5$ mm. Overall IC power consumption is equal to 520 μW @3 V (ADC: 160 μW, bandgap reference: 60 μW, voltage regulator: 60 μW).

2.2.9 A CMOS integrated circuit for multichannel multiple-subject biotelemetry using bidirectional optical transmissions (Kawahito et al., 1994) [34]

Application scenario
Continuous, non-invasive monitoring of the physiological state of human or animal subjects in space (e.g. inside a spacecraft) is becoming increasingly important not only for the well-being of the subjects but also for further studies on the effects of zero gravity on living organisms. In this paper, an implantable, mixed-signal CMOS IC for real-time, bidirectional, optical biotelemetry is proposed. The system is designed to support a maximum of 4 subjects with a maximum of 4 signal channels per subject. Sequential monitoring of all subjects is achieved by time-multiplexing of the biological signals. Pursued attributes of the CMOS are the small size, light weight, low power and EMI-free operation of the implant. A specific instance of the system is given that measures ECG (electroencephalography) and EMG (electromyography) signals.

General overview
The proposed system consists of one (up to four) telemetry units and an external (host) system for issuing commands to them and reading back physiological data. Their block diagrams are given in figures 2.8 and 2.9, respectively. Each issued command by the external unit, contains an ID of the subject (i.e. the telemetry chip) that is selected for data transmission.

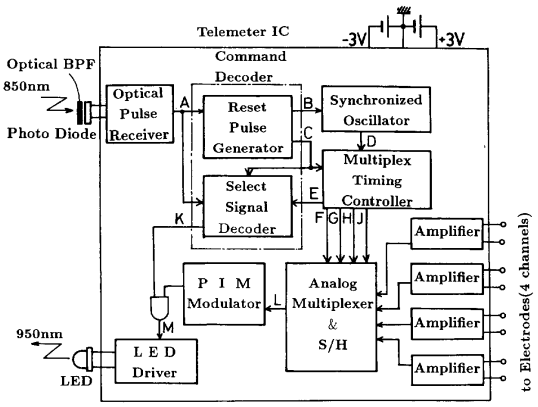

Figure 2.8: *Telemetry-unit block diagram.*

Implanted part
The telemetry unit is composed of the CMOS IC, an infrared LED (for data transmission, a PIN photodiode (for command reception) and two batteries (Fig.2.8). A command is received by the photodiode and is, then, amplified and wave-shaped to electrical pulses by the Optical Pulse Receiver. The photodiodes also include optical bandpass filters (bandwidth set to 50 nm). Each new command carries (among other fields) a sync pulse so that the system clocks of both the telemetry units and the external unit are always in phase. This sync pulse is detected by the Reset Pulse Generator which adjusts the oscillator circuit accordingly. It also generates a reset pulse for initializing the internal states of the telemetry unit properly. The

Multiplex Timing Controller, then, generates timed gating pulses for sampling the 4-channel amplified biological signals (and for detecting the subject selection ID from the command). The biological data are acquired through electrodes, amplified by low-noise differential amplifiers and time-division multiplexed by the Analog Multiplexer & S/H. If the implant ID matches the command ID, then the multiplexed data are pulse-interval modulated (PIM) and sent to the infrared LED for transmission. The PIM scheme is realized by an in-series connection of a PWM-modulator and a subsequent pulse-edge detector.

External part

The external system is divided in two sections: a transmitter section for generating and transmitting command signals and a receiver section for receiving, demodulating and demultiplexing the multiple-subject, multichannel telemetry signals (Fig.2.9). Both sections are synchronized.

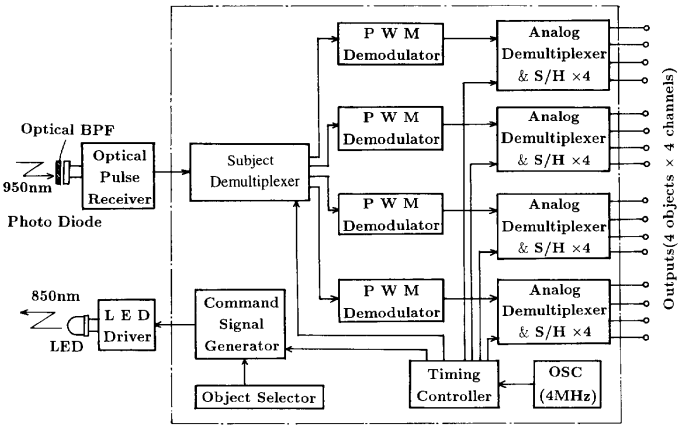

Figure 2.9: *External-unit block diagram.*

Communication scheme

It is a goal of the authors to achieve as low an EMI as possible for the telemetry system, therefore near-infrared light has been used instead of, say, RF signals. Pulse-interval modulation has been employed as the data modulation technique due to its low power dissipation (i.e. to reduce EMI further). The commands that are transmitted by the external unit are periodic and consist of synchronization and subject-selection signals (as previously mentioned). After these signals are transmitted (at a wavelength of 850 nm), time is allowed so that the selected telemetry unit has sufficient time to transmit back data from all four channels (at a wavelength of 950 nm) before a new command is issued. Real-time, multiple-subject telemetry is performed by selecting another subject at each new command. The effective sampling frequency of the system naturally depends on the number of subjects and the number of channels to be monitored (and the system clock). By selecting a 4 MHz clock, a sampling frequency of 1085 kHz (4 subjects, 4 channels) is used which is considered adequate for most biological signals.

Electromechanical specifications

The two batteries used are small-sized lithium batteries of 3 V (120 mAh). Most power of the telemetry unit is consumed by the LED driver since the IC power consumption is negligible by comparison. The mean power consumed by the LED is 7.5 mW (2.5 mA @ 3 V) for the case of a peak LED driving current of 50 mA and a PIM-pulse duty ratio of 5%. Therefore, continuous telemetry of 48 hours is possible. For proof of concept, the authors have implemented an IC with $5 - \mu m$ CMOS process technology. Its dimensions

are 5.1 $mm \times 5.1\ mm$ and it includes about 600 transistors. In this chip version only the biological-signal amplifiers are off-chip. Also, support for 2 subjects and 2 channels has been implemented and the telemetry unit has been tested on human subjects to measure ECG and EMG signals.

2.2.10 A high level language implementation of a general purpose telemetry system for biomedical applications (Rorie et al., 1996) [55]

Application scenario

This paper is another attempt, similar for instance to [33] (discussed in subsection 2.2.8), to implement a general-purpose biomedical-data acquisition and telemetry system for monitoring some physiological parameter(s) of a living organism. Flexibility is one of the main design goals of the authors which they are addressing through programmability of various parameters so as to allow for compatibility with a number of commercially available sensors. Without loss of generality, the authors have selected their demo application from the area of orthopaedic research which lacks long-term data on the structural integrity of artificial implants such as total-joint systems. It involves measurement of orthopaedic implant stresses using strain gauge sensors.

General overview

Typically, the proposed system consists of two main parts: the actual implant and the remote monitoring unit (RMU). The implant comprises a VLSI IC, a battery for power supply, an antenna and associated sensors for data acquisition (Fig.2.10. The RMU in virtue includes a communications RF transceiver connected to a host computer.

Implanted part

For the implantable unit, the authors identify the need to be *flexible* enough to support the specific need of the average biological sensor while at the same time being *customized* enough to exploit the full range of the device. This trade-off is achieved through the addition of programmability to the implant. The implant is implemented in CMOS technology due to its very low static power consumption and consists of a digital controller and an internal SRAM for sensor data storage. The controller design can be further broken down into a Control-logic block, a Communications interface, a Sample-Timing & Interface block and a Memory Controller for the SRAM.

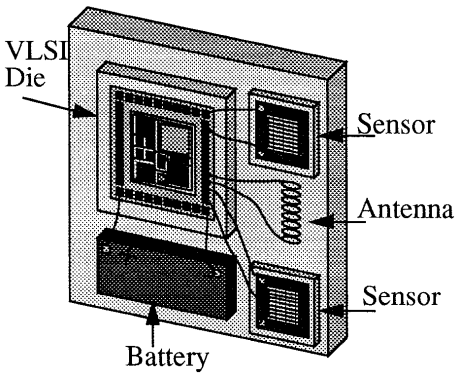

Figure 2.10: *Implant part of telemetry system.*

The Control logic is designed in microcontroller style in the sense that it receives and decodes discrete instructions and performs corresponding actions. These instructions

are transmitted to the implant by the RMU (to be discussed later). According to the authors, such a control design allows for modularity and easy expansibility. Special provisions for the long-term operation of the implant have been made by including extra power conservation logic. This circuitry consists of transmission gates and other peripheral logic distributed throughout the chip to control the flow of current. This is effectively achieved through power-up and power-down commands that the RMU can send to the implant. When in power-down mode, biasing current for the sensor and the RF transmitter portion is removed. Additionally, the system clocks are disabled and the only functional sections are the control logic, the communications interface logic and the RF receiver (in order for a subsequent power-up command to be detected).

Explanation of the functionality of the Sample-Timing & Interface block is coarse in this paper. It is, therefore, assumed that analog signals from attached sensors are sampled and analog-multiplexed before going through an ADC. This logic block is the controlling logic of the ADC and the multiplexer components, both of which are again assumed to be off-chip. Each sensor channel (in the current paper 4 channels are depicted) has a register attached that points to the desired sampling rate for that sensor. Also, to avoid data contention and to resolve race conditions among the sampled channels, a priority encoder is implemented which latches channel outputs in a deterministic order. Extra logic can effectively delay fast sampling sensors (operating at 32 kHz) so as to allow for longer monitoring periods and to prevent the on-chip SRAM from exhausting.

External part
No elaborate details are given for the external part of the telemetry system. The RMU encompasses a custom RF communications transceiver which is connected through an RS-232 port to a host workstation. The host is burdened with the task of receiving, processing, storing and visualizing the telemetered data. It is also responsible for synthesizing the instruction sequences for programming the implant. These instructions effectively define the number, speed and occurrence of the samples within the implant.

Communication scheme
Each command word sent from the RMU to the implant is 2 bytes long, received least-significant-byte first. Synchronization can be achieved through the leading bit of each transmitted byte. In this paper 15 commands have been implemented including power-up/power-down mode, test mode, SRAM read/write and data retransmission. The above mentioned digital controller also contains a so-called Transmission Verification logic (TVL) block to minimize the possibility of erroneous commands being accepted by the implant. The (redundancy) scheme implemented here is retransmission with complementation, i.e. each command byte is complemented and transmitted with the original to form a word. Then, if both bytes of such a word match, the implant acknowledges the transmission back to the RMU. In case of corrupt data, retransmission occurs.

Electromechanical specifications
In this paper, the authors identify the size-constraining nature of batteries for implanted devices. Nevertheless, the emphasis is on the IC itself so only assumptions

are made regarding the availability of reasonably priced, self contained batteries which are suitable per application scenario. Various architecture implementations have been attempted for the proposed telemetry system utilizing schematic-capture, physical-level and behavioral-level design. Typical figures of a design with enhanced functionalities are size of 2500 μm $\times$ 2500 μm and CMOS fabrication process of 0.8 μm (Hewlett Packard). Power consumption or, at least, power estimation by the design tools, is also not discussed.

2.2.11 A hybrid analog and digital VLSI neural network for intracardiac morphology classification (Coggins et al., 1995) [14, 15]

Application scenario

Implantable cardioverter defibrillators (ICDs) are devices that monitor cardiac rhythms through ventricular and/or atrial leads and detect the potentially fatal ones. In case such a rhythm is detected, the ICD administers (electrical) pacing or shock therapy to the patient. Contemporary ICDs use *time-based* decision trees for cardiac arrhythmia classification. However, timing analysis alone cannot distinguish among all rhythms for all patients, thus, calling for a more elaborate morphology analysis for complete diagnosis, such as correlation waveform analysis. The problem with such methods is that they are too computationally intensive to meet the strict power requirements, especially when implemented in software on an implant's mP.

For this reason, the authors are proposing an analog VLSI neural network (NN) for performing cardiac rhythm classification tasks. With such an approach they aim at very low area and power requirements for the resulting system. It should be noted that the current paper presents a mixed-signal CMOS chip for implementing the NN and not a total ICD system. The training scheme used for the NN is also discussed.

General overview

In this paper, the authors focus on the successful distinction between Sinus Tachycardia (ST) and Ventricular Tachycardia (VT) with 1:1 retrograde conduction. While ST is a safe arrhythmia occurring, for instance, in cases of vigorous exercise, VT can be potentially fatal. Both rhythms are characterized by a heart rate of approximately 120 *beats/min*. Since the morphology change between the two rhythms resides predominantly in the QRS-complex, the study is mainly concerned with successfully

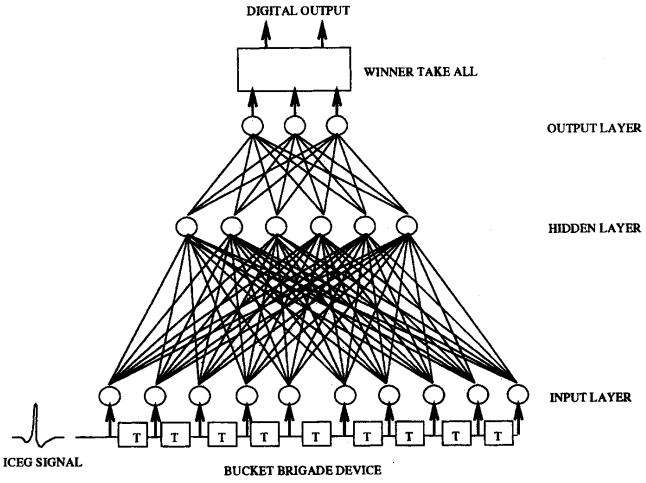

Figure 2.11: *Functional diagram of the chip.*

tracking differences in this region of the total beat period.

The CMOS IC consists of a bucket-brigade device (BBD) which effectively is an analog shift register, a 10:6:3 multilayer perceptron and a winner-take-all circuit (Fig.2.11). In the figure, circles represent neurons and lines represent synapses. Also, the output of the chip is digital and the NN weights are digitally stored on-chip. No external host is discussed apart from a computer with appropriate interfaces which has been set up for performing initial training on the NN of the chip and for testing its performance.

Implanted part
The BBD is an analog delay line which samples the intracardiac electrocardiogram (ICEG) signal at a rate of 250 Hz and feeds data to the first level of the NN. The two clocks that the BBD requires are generated off-chip and are controlled by a QRS-complex detector signal which is provided by the ICD device.

The NN is a multilayer perceptron with an input layer of 10 neurons, one hidden layer of 6 neurons and an output layer of 3 neurons. The output of a neuron in each level $l+1$ of the perceptron is given by: $\alpha_i(l+1) = f\left(\sum_{j=1}^{N_l} w_{ij}\alpha_j(l)\right)$, where N_l is the number of neurons in layer l, i is the neuron index, w_{ij} is the weight connecting neuron j in layer l to neuron i in layer $l+1$ and f is the utilized neuron squashing function. The synapse circuit has weight storage of 5 bits plus sign bit. Bias reference (which is required for the synapse circuit) is derived from a weighted current source in the corner of the chip. For the neuron circuit, in order to cope with problems rising from the high fan-in (such as common-mode cancellation), appropriate schemes are implemented and the neurons are set to operate in the linear part of their transfer functions. Finally, in this paper a two-class problem is encountered (ST or VT), therefore the winner-take-all circuit simply implements a thresholding function. (The two unused neurons of the output layer have been disabled by setting their input weight to zero).

External part
As previously mentioned, there is no external part to the described system, save for the computer setup implementing the initial NN training and testing. The PC uses appropriate hardware (PC-LAB) for providing digital and analog I/O to the chip. It plays the ICEG signal to the input of a commercial ICD in real time. The ICD performs bandpass filtering and QRS-complex detection to the signal. In turn, the QRS-complex detection signal is fed to the chip for freezing the BBD clocks so that a classification can take place. During the training process, analog chip outputs are sent to the PC which then adjusts the NN weights accordingly by writing to the digital input of the chip. On-line training is used for training the NN; thus, small adjustments to the weights are done per each new QRS-complex[3]. The algorithm used for weight adjustment is *summed-weight node perturbation*. The system was trained on seven different patients separately, all of which had VT with 1:1 retrograde conduction.

[3]Contrary to on-line training, batch-mode training is performed by making a single weight adjustment after all patterns have been fed to the NN. On-line is obviously faster than the latter method but it does

Communication scheme
There is no communication scheme implemented since there is no external part to this system. All connections of the chip to the PC during training, have been described above.

Electromechanical specifications
The overall IC power consumption is 186 nW at 3 V (comprising 18 nW for the required system buffers, 128 nW for the overall NN and 40 nW for the BBD at the specified sampling frequency). The IC was implemented in 1.2 μm CMOS technology and has an area of 2.2 mm $\times$ 2.2 mm.

Miscellaneous issues
The choice of using analog circuits over digital ones was based on the desire to meet strict power and area requirements of implantable devices. The inherent problems of analog approaches such as noise, drift and offsets are alleviated to a large extent through the use of the NN. With training the NN becomes robust not only to noise and offsets contributed by the neourons/synapses but also to noise and distortion in the training patterns due to the transmission and processing by the ICD. It should be noted that the NN circuitry is very sensitive to drift problems also due to temperature variations, yet no temperature compensation scheme is required as the human body is a stable thermal environment. The system performed as follows: on average 95% true positive and 97% true negative detections have been made. Future improvements include continuous adaptation of the classifier NN since rhythm morphology may change over time due to drug therapy or tissue growth.

not affect the system, since the bottleneck exists in ICD filtering and QRS-complex detection, both performed in the ICD.

2.2.12 A low power multi-sensor interface for injectable microprocessor-based animal monitoring system (Wouters et al., 1994) [71]

Application scenario

The authors identify the current need for reliable and implantable telemetry sensor systems featuring small size, light weight, long operational lifetime but also increased flexibility, versatility and intelligence. They specifically aim at injectable devices for large-scale, animal-husbandry applications (welfare and climatic-control systems). The injectability aspect calls for extra constraints such as extreme miniaturization and ultra low power consumption, which - up till now - have been dealt with by keeping proposed designs rather simplistic.

Nevertheless, it is the authors' wish to propose such monitoring systems that do more than barely cover the per-case specifications. They achieve increased intelligence and multi-purpose use of implantable transponders by including a miniature, off-the-shelf mP and a custom mixed-signal CMOS IC that implements a generic Sensor Interface Chip (SIC).

General overview

The overall system is depicted in Fig.2.12. The implanted component is designed to be injected at the ear base of an animal. This is the telemetry (transponder) device which monitors physiological data on the animal through various sensors and transmits them to an external system over an RF link, on demand. For this application scenario, the transponder has been designed to support two sensory subsystems, a temperature sensor (using a commercial SMD[4] thermistor) and two physical-activity detection sensors (using subminiature capacitive accelerometers). The external system consists of an antenna and decoder unit which communicates with a personal computer over a serial link. The computer is responsible for processing and storing interrogated data but also configures the operation of the implant.

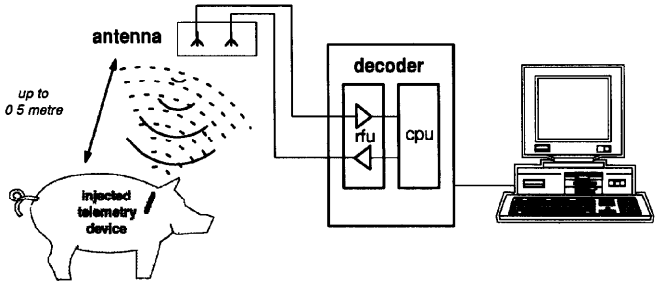

Figure 2.12: *Overall telemetry system.*

Implanted part

A simplified block diagram of the injectable transponder is given in Fig.2.13. Four main building blocks are distinguished. The first part is the mP (Philips PCD3343A) and is responsible for telemetry control, communication with the SIC and the outside world, reading monitored

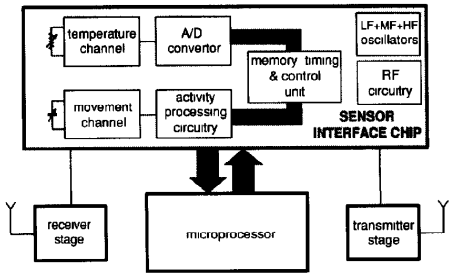

Figure 2.13: *Block diagram of injectable system.*

[4]Surface-Mountable Device

data from and writing programming settings to the SIC. Even though this is a small-size mP, it still consumes too much power for this type of application; therefore, the authors make special provisions for its use in the system (e.g. the mP is in sleep mode for most of the operation cycle). Desired traits of the mP are the increased intelligence of the system and its ability to store data in the on-chip (mP) memory. The second part of the transponder is the SIC which combines several functions (as seen below). Its analog circuitry includes two sensor interface channels (for the two sensors). It also incorporates three (LF, MF and HF) oscillators, RF modulation/demodulation circuitry and a fully integrated battery-check circuit. The digital part consists of an ADC, local memory, a finite-state controller, a (hardware) movement-processing algorithm for the accelerometer readouts, several timing functions and clock control circuits. The remaining two building blocks of the transponder are the receiver and transmitter stages for communicating with the external system, both of which consist of tuned LC tanks.

The three different types of oscillators control all timing of the transponder. The LF oscillator, running at 64 Hz, is an extremely low-power circuit (150 nA @ 3 V) for general and basic timing of the monitoring actions (i.e. determines sampling intervals). The MF oscillator runs at 85 Hz and controls the actual monitoring functions when the SIC is active. The HF oscillator is the 45 MHz clock for the mP. All communication between the SIC and mP is initiated by the SIC and controlled by the mP. Data are shifted serially in and out of the SIC. To preserve battery power, the mP and its $45 - MHz$ clock are always in sleep mode. They are only woken up by the SIC when either one of two events occurs: an external command (through an RF carrier) for data telemetry is detected or a signal indicating availability of SIC monitored data and ready to be read by the mP is triggered. On wake up, the mP detects the source of the disturbance, will perform the appropriate action and will, then, go back to sleep.

The SIC has three operation modes. The first one is the *normal monitoring mode*, controlled by its own FSM. In this mode, all SIC circuitry is in standby and when a user-defined sampling interval elapses, a measurement is performed. Again, three types of measurements are possible (and selected by the external user), namely temperature measurement, detection of physical activity and battery voltage-level check. When measurements are finished, the mP is woken up, data are stored in its memory and the whole process is repeated. The second mode is the *telemetry mode* and is activated when the RF receiver (connected to the SIC) detects an external command. The SIC will forward the decoded command to the mP. If bidirectional communication needs to be established, the mP will - in turn - encode data and forward them to the SIC for transmission to the external system. The third mode of operation is the *SIC programming mode* in which the mP reprograms the SIC on user request. Up to 16 different commands can be used to program the SIC. This mode effectively offers the versatility and intelligence of the proposed system. With these commands the external user can control the operational modes of the SIC, can calibrate and adjust the monitoring channels and oscillators or compensate for sensor drift and low battery level and can, finally, adjust analog components such as temperature and movement channel sensitivity, voltage references and current sources.

As far as measurement circuitry is considered, the temperature measurement consists of an $8-bit$ ADC after amplification by a low-power instrumentation amplifier. Movement detection is more complex, though, since single measurements cannot reveal information about the physical activity of the animal. Therefore, a specific algorithm has been implemented in hardware which monitors the animal activity over a user-defined period of time. In so doing, 1 *byte* of information is given (per measurement) revealing the percentage of (monitored) time during which the animal had a certain (user-defined) degree of activity. Finally, battery voltage-level measurement produces another *bit* and sets it if this level is lower than a specific user-defined level.

External part
The external system simply comprises a personal computer which serially controls a decoder unit with separate antenna. The decoder is a dedicated, microprocessor-based unit (Eureka Company) which interrogates and reprograms the injected transponders. Received telemetry data are stored in the computer.

Communication scheme
According to the authors a fully custom communication protocol has been built between the implanted transponder and the external system. The implant is activated by an incoming ASK carrier modulated at 132 kHz and, after performing operations as seen above, it transmits stored data using a $66-kHz$ ASK (or PSK) modulated carrier derived from the incoming frequency.

Electromechanical specifications
Since the implant is designed to be injected in the ear base of an animal, it is housed in a cylindrical package having a length of 40 mm and an external diameter of 5 mm. Due to low-power and small-size constraints, a low-voltage $(3-V)$ SIC has been developed. 2 μm n-well CMOS process has been used. The SIC dimensions are 9.97 $mm \times$ 2.68 mm. All electronic components of the IC have been placed on a $200-\mu m$, double-sided, through-hole printed, thick-film alumina substrate. During monitoring, the mean power consumption of the overall implant is 75 μW (25 μA @ 3 V) and during transmission is 12 mW (4 mA @ 3 V). A small lithium battery of 20 mAh has been used, effectively providing a lifetime of more than 6 months.

Miscellaneous issues
It should be noted that the authors attempted to shift as much intelligence as possible, related to monitoring, calibration and signal processing, towards the SIC to make it as independent as possible from the mP. Naturally, the inclusion of a separate mP in the design signifies a "sharing" of this intelligence between software (mP) and hardware (SIC).

2.2.13 A low power VLSI neural network based arrythmia classifier (Shawkey et al., 1998) [62]

Application scenario
This paper is also occupied with the ICD problem of correctly distinguishing among cardiac arrhythmia cases the potentially fatal ones for the patient. Successful detection is of utmost importance since a misinterpreted arrhythmia could result in the ICD wrongly applying electrical stimulation to the patient. The authors are proposing a low-power VLSI Kohonen-NN chip which acts as an intracardiac tachycardia classification system. Advantages of this approach - apart from low power consumption - are small area, easy interface to analog ICD signals and fault tolerance. This design is an alternative approach to a problem previously addressed, for instance, by [14], [15] (see subsection 2.2.11).

A typical case of cardiac rhythms that are difficult to classify by using simple timing methods is the pair ST and VT with 1:1 retrograde conduction. Both of them have a rate of 120 beats/min, nonetheless ST is a safe arrhythmia whereas VT is potentially fatal. The authors, similarly to other researchers, are studying only the QRS-complex region of a cardiac beat period for morphology changes, it carrying the most differences between ST and VT.

General overview
The VLSI chip comprises three main stages: an operational amplifier (op-amp) followed by a sample-&-hold delay circuit and, then, by the NN classifier. The NN is of the off-chip learning type which means that an external system is probably also needed to train the NN. Other than that, there is no mention of any further external system setup (e.g. computer) for communicating with the chip.

Implanted part
The ICD signal to be classified is, first, input to the two-stage op-amp with improved noise and offset performance. The amplified output is, then, forwarded to the ten-stage sample-&-hold delay circuit which allows for five pulses per pulse to be fed to the NN classifier (which is sufficient for the needed task). This circuit utilizes two non-overlapping clocks which are generated on-chip.

The NN classifier is based on a Kohonen self-organizing map (KSOM). The KSOM consists of 2 groups of synapses and 2 neurons (see Fig.2.14). The 2 leftmost circles are summation nodes ($\sum$), the other 2 are neurons and the lines are synapses. The first group of synapses with weight vector $W = [w_{11}, w_{12}, ..., w_{15}]$ is connected to the first summation-neuron pair while the second group with weight vector $W = [w_{21}, w_{22}, ..., w_{25}]$ is connected to the second pair. Each neuron corresponds to a class

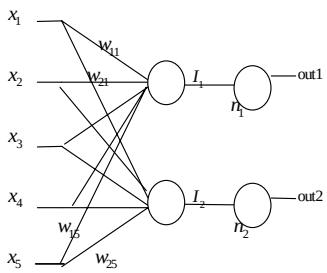

Figure 2.14: *Kohonen self-organizing map classifier neural network.*

(ST or VT) of the inputs. If $X = [x_1, x_2, ..., x_5]$ is the input vector, then the *best-matching criterion* selected by the authors for classification is the minimum distance between X, W, namely: $min\|X - W_j\| = \sum_i (x_i - w_{ji})$, where $j = 1, 2$ is the number of classes and i is the best-matching neuron ($i = j = 1, 2$). As synapse circuits, operational transconductance amplifiers (OTA) are used which effectively perform the difference between an input x_i and a weight w_{ji}. Based on the above, the neurons for the KSOM need to act as comparators (i.e. op-amps). For an ST input, one neuron outputs '1' and the other '0'. The results are reversed for a VT input.

External part
No information on any external system is given. It is only mentioned that NN training is performed off-chip and the (trained) weights are written to the corresponding synapses using a DC-level shifter.

Communication scheme
No information is given regarding communication of the NN chip to any external system.

Electromechanical specifications
According to the authors, the VLSI chip is designed to consume "typically a few milliwatts", yet no specific power figure is given throughout the paper. Also, the fabrication technology used is not mentioned save for the fact that this is a mixed-signal, CMOS VLSI integrated circuit.

2.2.14 A multichannel neuromuscular microstimulator with bidirectional telemetry (Nardin et al., 1995) [47]

Application scenario

Functional Neuromuscular Stimulation (FNS) has been successfully used for restoring function in various application scenarios including stimulation of paralyzed muscle. Implantable FNS microsystems have been introduced in medicine some time ago which receive RF telemetered power and commands and apply corresponding pulses to the patient. However, the authors propose in this paper a new neuromuscular microstimulator which bears more than a single stimulation channel (up to eight) and can deliver programmable amplitude and duration current pulses. Since FNS devices cannot be easily monitored or removed, the authors emphasize on building a system encompassing high reliability in order to minimize failure chances and, effectively, surgery. They address reliability by supplying the FNS system with bidirectional telemetry capabilities so that it can "answer back" information regarding its package integrity, data transmission errors etc.. Of course, ever-present issues of low power and small size (the aim is for an injectable device) are also taken into consideration.

General overview

The presented overall system has a typical layout; it consists of an external control module which wirelessly communicates with an implanted component - the microstimulator. A block diagram of the system is depicted in Fig.2.15.

Implanted part

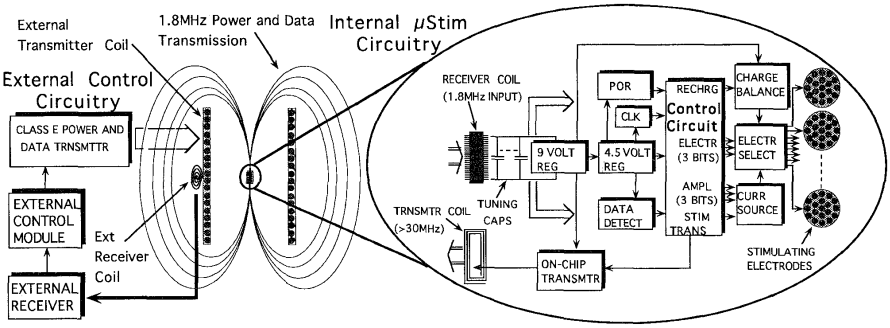

Figure 2.15: *Block diagram of microstimulator system.*

Functionally, the microstimulator consists of an IC chip (which includes the control logic for the implant), receiver and transmitter circuitry and a hybrid capacitor used for charge storage of the stimulation pulse. The IC chip is used for data reception and transmission and for microstimulator control. The latter task is performed by decoding received commands and building a programmable constant current output pulse for muscular stimulation when appropriate. The IC chip also includes appropriate low-power voltage regulators which generate regulated voltage supplies for normal chip operation from the RF-radiated power (to be discussed later) and clock recovery circuitry. Furthermore, a data decoder is implemented which employs a differential input current-mode operation for reliable data demodulation and, finally, output drivers for the stimulation electrodes. The chip can deliver current pulses into tissue through those eight electrodes with programmable ampli-

tude in the range $1.25-10\ mA$ by $1.25-mA$ steps and duration in the range $1-512\ \mu sec$.

The receiver front end is a hybrid receiver coil which (along with the charge storage capacitor) is mounted on the IC chip. The transmitter is an on-chip circuit which consists of a coil and active driver. The coil is based on a custom fabrication process which performs proper electroplating of base and metal on a wafer to form the coil structure.

External part
Little information is given about the external control circuitry. As seen in Fig.2.15, the external setup comprises a class E power and data transmitter and a receiver module.

Communication scheme
The microstimulator receiver power and data from an amplitude-modulated RF carrier signal through an inductively coupled link. It is this RF carrier that is utilized to generate the regulated voltage supplies inside the IC and to recover a clock signal. The external transmitter operates at 1.8 MHz carrier frequency whereas the on-chip transmitter of the implant operates at a nominal frequency of 33 MHz. For reliable transmission of the data component of the RF link, a full data transmission protocol has been developed by the authors. In case of erroneous data reception, the implant does not advance in operation hinting the external control of the error. Only in case of meaningful data reception does the implant acknowledge back the command. To make the system even more fault-tolerant, parity checks have been added in the transmissions and also (correct) received information are transmitted back for comparison. External commands might include information regarding self-test settings as well as stimulation-channel selection or pulse width and amplitude configuration.

Electromechanical specifications
A $3\mu m$, 2-poly, single-metal BiCMOS fabrication process has been used for the IC chip which has a size of 1.4 $mm\ \times\ 13.5\ mm$ (keep in mind it is designed as an injectable implant). It contains 2800 devices and consumes approximately 40 mW with an AC input voltage of 20 V. The clock and logic circuitry were designed to operate at a frequency of 2 MHz but they have been tested to work at more than 4 MHz. A glass capsule has been used to contain the IC and all hybrid components.

2.2.15 A passive humidity monitoring system for in-situ remote wireless testing of micropackages (Harpster et al., 2000) [30]

Application scenario
This paper is involved with hermeticity issues of implantable medical devices. To assess the suitability of a particular miniature package for a specific application, various testing methods have been developed to determine mean-time-to-failure by creating an accelerated test condition. However, many applications require that the package is tested in its real environment and/or that it is continuously monitored in-situ. This is particularly the case for many biomedical applications since it is not possible to accurately reproduce biological conditions in-vivo. For these reasons, the authors are proposing a high-sensitivity humidity sensor for monitoring package hermeticity as well as telemetric circuitry for passive wireless transmission of monitored humidity.

General overview
The suggested system is simply a humidity sensor and a transmitter circuit for sending data to the outside world (Fig.2.16). There is no explicit information given regarding any attached external system for processing or storing of sensor readouts.

Implanted part
The humidity monitoring system is conceived as an addendum to other medical implantable systems that need to be hermetically isolated from any surrounding living tissue. To this end, the authors have designed and evaluated the performance of a miniature, high-sensitivity, capacitive, humidity sensor whose output is directly fed to a hybrid transmitter for wireless reception of data. The transmitter circuit is, in virtue, a hybrid coil wound around a ferrite core, forming an LC tank circuit. The resonant frequency of the LC circuit is determined by the sensor capacitance which changes in response to to humidity. The monitoring system can measure resonant frequencies in the range $\pm 12.5\ kHz$ giving an overall resolution of $\pm 2.5\%$ RH (Relative Humidity).

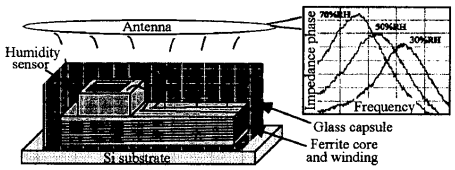

Figure 2.16: *Passive humidity monitoring system.*

External part
No information is given about any specific external data-accumulating station. Mentioned is only the fact that a circular loop antenna is externally used to inductively power the sensor circuit and stimulate it to transmit data back.

Communication scheme
Over the wireless link, power is transferred inductively from the external antenna to the implant. Information transfer from the sensor back to the antenna is achieved based on the load-impedance reflection phenomenon: Since the capacitive component of the LC tank is the humidity-sensor capacitance, it is obvious that humidity affects circuit load impedance. Then, according to basic electronic circuit theory, the implant load is

"reflected" in the transmitter antenna circuit (due to the established mutual induction). A change of the impedance in the (external) antenna circuit shall result in a change in the antenna current which is easily measured.

Electromechanical specifications
The proposed monitoring system has dimensions: $7\ mm \times 1.2\ mm \times 1.5\ mm$ and has been encapsulated in a glass-silicon package.

Miscellaneous issues
The implant has been tested in-vitro, in both normal and accelerated conditions, and in in-vivo, by implanting devices in the scull, the leg and the abdomen of guinea pigs with successful performance of the humidity sensor. Also in this paper the authors actively study the effect of distance between coupled components on the measured frequency. They show that the use of a ferrite-core antenna boosts both measurement distance $(0.2 - 2\ cm)$ and sensitivity. However, while phase amplitude benefits from the core, resonant-frequency shift phenomena appear.

2.2.16 A programmable mixed-signal ASIC for data acquisition systems in medical implants (Lerch et al., 1995) [38]

Application scenario

This paper is another approach towards developing generic implantable data-acquisition systems. It is the authors' strong belief that such implantable microsystems can offer - in the years to come - an alternative means of convenient, stress-free and cheap medical diagnostic methods for the patients. Towards this end they are presenting a programmable mixed-signal ASIC for physiological-data measurements. For the purposes of this paper and as a first application, they implement a system for the acquisition of *ECG*, *heart-muscle elasticity* and *electrolyte-composition data of transplanted hearts*. This system allows daily collection and transmission of data over a bidirectional RF link to an external host system.

General overview

The data acquisition system consists of the programmable implant and the external system vaguely referred to as the "local host". This host is responsible for issuing commands and gathering data from the implant and communicates with it over an RF link. It forwards collected data to e.g. a remote hospital computer via a modem.

Implanted part

The implant is depicted in Fig.2.17. The electronics are integrated on a multi-chip module (MCM) that carries the mixed-signal ASIC, a program ROM, up to 128 kB of RAM for storing sampled data, an $8-bit$ ADC, a $2.5-V$ reference circuit, RF circuitry, a DC/DC converter (for powering the implant from a battery) and other required decoupling and safety modules (not shown in the figure).

The ASIC encompasses an analog part and a digital part, the former fully controlled by the latter. The analog part consists of three amplifier/filter channels (one high-speed and two low-speed ones). The first (high-speed) channel is clocked at 128 kHz and is used to amplify voltage response of the heart tissue after current excitation. The second channel operates at 8 kHz and is optimized for ECG-signal conditioning. It has an amplification of up to 66 dB and switchable 50 Hz and 100 Hz biquad notch filters to reduce noise from power lines. The bandwidth is limited by a biquad, low-pass filter to 1 kHz. The third channel is similar to the second one and is designed for the output of the heart muscle motion ("wall motion") sensor. Its maximum amplification is 80 dB and the bandwidth can be limited to 50 Hz or 120 Hz for noise reduction using a programmable

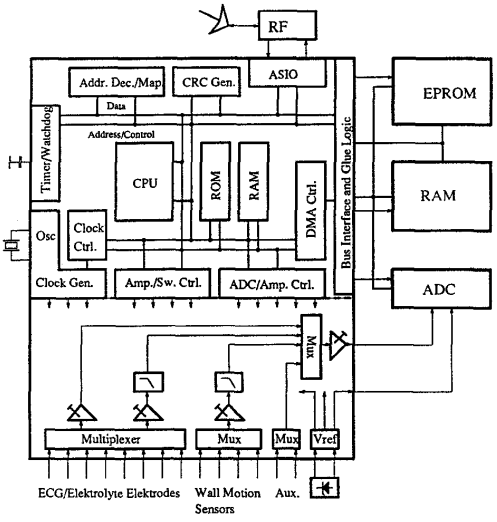

Figure 2.17: *System block diagram.*

T-cell, low-pass filter. All amplifiers and filters use the switch-capacitor technique. The front end of the amplifiers consists of 9 ECG electrodes and 2 wall-motion sensors. Auxiliary inputs are used for system observation, e.g. battery power, sensor supply lines etc.. There are some extra peripheral analog blocks that are also integrated on-chip like reference-voltage buffer and sensor current-supply circuitry. Hybrid analog components are the half-flash $8-bit$ ADC and a bandgap reference circuit.

For the digital part, an embedded $8-bit$ mC core with 192 *bytes* of RAM is used. The mC along with a small boot ROM and a CRC generator implements necessary system self-tests and diagnostics on power-up. Program safety is ensured by software and by hardware (i.e. two watchdog timers) techniques. A simple DMA unit has been implemented to disentangle the CPU from the task of data acquisition. In general, the mC is used only for higher functions during measurement initialization and communication. This fact permits stopping the clocks for more than 85% of the time and, also, lowering their frequency to 128 kHz due to reduced load. The clocks of the dedicated hardware can be stopped for about half the time. At the analog part, all unused amplifiers and filters can be switched off independently at a central bias generator. It should be noted also that the MCM has been built to support scan-based testing and debugging with hardware breakpoints. Communication with the local host is achieved through a half-duplex, asynchronous, serial interface and attached FSK modulator.

External part
No information is supplied for the external host other than the fact that it is responsible for wirelessly stimulating the implant to take measurements and, subsequently, for collecting back the sensory data and forwarding them to a remote hospital (via a modem).

Communication scheme
The communication scheme for the described system is as follows: the implant is initially powered down. Then, the host sends a wake-up signal to it over the RF link. After running self-diagnostic tests, the implant requests a command transfer from the host and performs requested measurements accordingly. Finally, it sends the physiological data back and shuts itself down. FSK modulation is used by the implant for transmitting back to the host. No details are given for the host-to-implant communication.

Electromechanical specifications
The ASIC is fabricated in a standard 1.5 μm CMOS process and comprises a $70,000$-transistor digital and a $5,000$-transistor analog part on a 85.4 mm^2. As described above, the system implements mechanisms for minimizing power expenditure given the fact that the implant operates on a lithium battery power source. In this way, average power consumption over a typical measurement cycle is equal to 3.9 mW (@ 3.3 V).

2.2.17 A telemetrically powered and controlled implantable neural recording system with CMOS interface circuitry (Akin et al., 1994) [1, 2]

Application scenario

Multichannel recording of neural activity from the central (CNS) and peripheral (PNS) nervous system has long been pursued by physiologists as a means of understanding the operation of individual neurons, of deciphering the organization and signal processing techniques of biological neural networks and of controlling a variety of prosthetic devices. Silicon micromachining and IC fabrication techniques have been used to produce recording probes for interfacing with the nervous system using percutaneous connectors for power and data transfer. Clearly, the use of wires and cables can cause infection problems and they are not suitable for chronic recording applications. Furthermore, so far, solely analog circuitry has been used for amplification, multiplexing and transmission of recordings. To enhance signal-to-noise ratio, to enable higher data compression and bandwidth and, on an overall, to increase system reliability, digital methods need to be introduced.

Based on the above observations, the authors are proposing a mixed-signal VLSI IC for implementing a telemetrically powered and communicated recording system for chronic application. On a monolithic chip the system combines signal conditioning, low-power A/D conversion, bidirectional user interface and RF telemetry units for power/data transfer.

General overview

The overall system consists of the passive, neural-recording implant itself and an external user-controllable host for initiating and coordinating operation of the implant. This host is a microcontroller board (Motorola 6811) which generates serial data for modulating a high-efficiency class-E transmitter which drives a circular transmitter coil. The system layout is depicted in Fig.2.18.

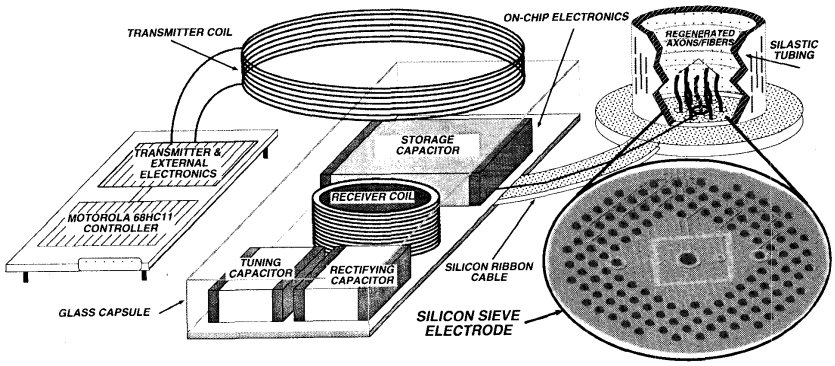

Figure 2.18: *Neural-recording-system architecture.*

Implanted part

The implantable component of the system contains both analog and digital parts. A block diagram is given in Fig.2.19. Analog circuits are developed on-chip for two purposes: for implementing the RF telemetry interface and for signal processing of the measured physiological data. The former comprises, firstly, of a voltage regulator which

generates the supply necessary for powering the implant. It generates a $5-V$ supply voltage by rectifying and regulating the induced, $20-V_{peak}$ RF carrier across the receiver coil. Secondly, a current-mode envelope detector circuit is designed for obtaining the AM-modulated information signal by filtering out the carrier signal. Provisions have been made towards low-power design and IC-transistor protection (against high DC levels of the RF carrier). The RF interface is completed with a clock-generator circuit which, in effect, extracts a clock signal also from the received RF carrier. This circuit is required for providing a clock signal for the control circuitry (to be discussed below) and for synchronization during data transmission.

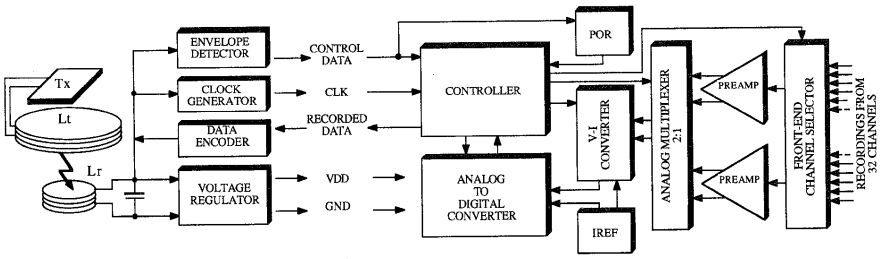

Figure 2.19: *Device block diagram.*

For the signal-processing capability of the chip, apart from analog components, also a (digital) controller is designed and utilized. This controller has been optimized for low power and is responsible for decoding received commands from the external (Motorola) controller and for forwarding digitized recorded data back to it. In order to simplify the design and layout process, the authors have used *delay elements*. A micromachined, sieve electrode has also been designed by the authors and attached to nerve axons which then have been allowed to regenerate into it. In this way, multiple neural recording channels have been created (up to 32). As seen in Fig.2.19, at any given measurement cycle, 2 out of 32 channels are selected for transmission to the outside world. To this end, two preamplifier circuits have been designed on-chip which can amplify neural signals with $\pm 500\ \mu V$ amplitude range. Each preamplifier has an in-band AC gain of 40 dB with a $3-dB$ bandwidth of 100 Hz to 3.1 kHz. It also has a DC gain of -40 dB which is critical in preventing amplifier saturation due to input offset and DC drift. An algorithmic, $8-bit$ ADC is used for data conversion. Current-mode design is used to minimize power consumption. Algorithmic conversion is achieved by multiplying the input current by two and then comparing it with some reference current. If the difference is positive, then the bit output is "1", otherwise the bit output is "0", and the difference is fed back to the circuit to determine the next bit. Finally, two other analog components of the VLSI chip are the current- and voltage-reference circuitry and a voltage-to-current (VI) converter. The latter is necessary for generating the current the ADC requires. The converter provides an accuracy better than 0.08% (which is an accuracy larger than 9 *bits*).

External part

As previously mentioned, the external part of the system consists of a microcontroller board which allows the user to send channel-selection commands to the implant and receiving back recorded data through a class-E transmitter and circular antenna.

Communication scheme
For achieving telemetry reliability a specific communication scheme has been implemented by the authors. It supports two subsequent modes of operation: *write address* and *read data*. Digits "1" and "0" are encoded by long and short pulses, respectively. When the external host transmits a "write" command to the implant, it also transmits a $10-bit$ address (5 *bits* per channel) of the 2 channels to be selected for recording and the implant stores it. The host can, then, transmit a "read" command and wait for a response. The implant performs A/D conversion to the recorded data (based on the two addresses stored earlier) and transmits back 16 *bits* of data (8 *bits* per channel). This communication scheme allows easy synchronization and gives control of the sampling intervals to the external user. It also is compatible with the selected RF telemetry system, which uses AM modulation. Back telemetry of data is achieved by the implant transmitter coil inducing an AC-voltage signal across the receiver coil (impedance reflection scheme), effectively modulating the incoming RF carrier (during the read-data mode).

Electromechanical specifications
The fabrication process used for the CMOS chip is 3 μm, p-well, single-metal, double-poly BiCMOS. It occupies 4 $mm \times 6\ mm$ of area, contains more than $5,000$ transistors and dissipates 15 mW (@ 5 V) of power operating at 1 MHz. The size of the total implantable unit including three hybrid capacitors and the receiver coil measures $5\ mm \times 8\ mm \times 2\ mm$. The unit is placed in a protective glass capsule.

Miscellaneous issues
The described system appears in two conferences, namely: "IEEE Proceedings of the Mediterranean Electrotechnical Conference (MELECON)" and "The 8th International Conference on Solid-State Sensors and Actuators, and Eurosensors IX". Here, the former is presented [1].

2.2.18 A telemetry system for the study of spontaneous cardiac arrhythmias (Rollins et al., 2000) [54]

Application scenario
The characteristics of spontaneous cardiac arrhythmias leading to sudden cardiac death are largely unknown. Towards capturing and correctly assessing all events preceding any sudden-death incident, the authors have developed an implantable radio-telemetry system for continuous monitoring of ECG signals over a period of weeks to months, with maintenance restricted to changing batteries.

Since this system has been designed for implantation into 20-kg animals, a primary goal has been the telemetered data acquisition. In this way stress conditions and Autonomic-Nervous-System (ANS) modifications to the test animals are avoided (e.g. no tethering of the animals is required). Another actively pursued goal is high temporal and spatial resolution of acquired data; therefore, the authors deliver an implant that supports 8 measurement channels, each at 1 kHz sampling frequency. Extra goals have been easily accessible battery change, liberal use of standard components and convenient archiving, retrieval and analysis of data. A similar approach for continuous ECG-signal measurement has been proposed by Enokawa et al. (see subsection 2.2.2).

General overview
The design of the system centers around two separate but inter-dependent units: the implantable unit and the backpack. Concisely, the implant consists of the analog and digital circuitry for recording data and transferring it to the backpack through *percutaneous* cables, whereas the backpack holds batteries for powering the implant, a processor and a WLAN-card for forwarding the data wirelessly to a base station for further archiving and analysis. An overview of the system is depicted in Fig.2.20.

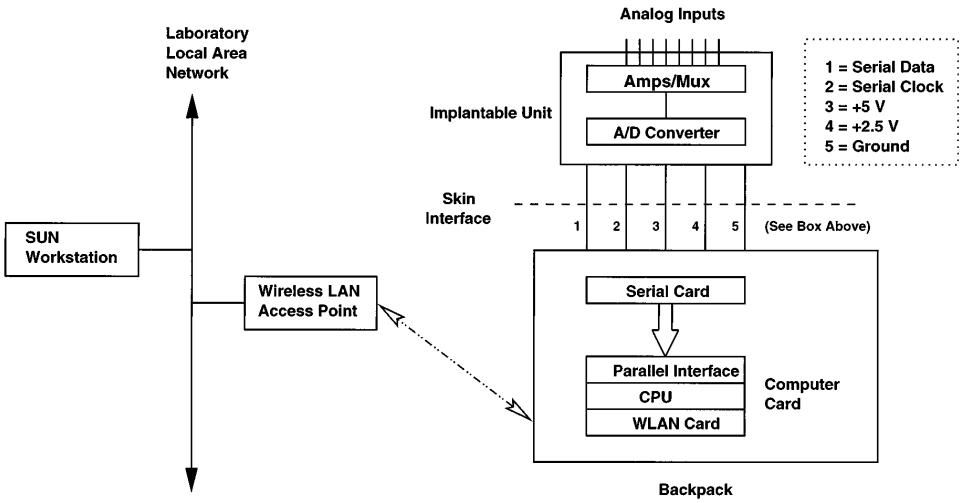

Figure 2.20: *Block diagram of telemetry system.*

Implanted part
The implantable unit supports 8 unipolar analog inputs (with the metal casing of the implant acting as the other pole). Each channel has a *total* gain of 50 and an input

range of $\pm 50\ mV$. The inputs are AC-coupled (for removing the DC component) and signal boost with a gain of 25 is performed. Then, each signal passes from a low-pass, active filter with a cut-off frequency of 260 Hz and a gain of 2 (thus resulting to the total of 50). The 8 channels are time-multiplexed and fed into a low-power, serial, $12-bit$ ADC (AD7853, Analog Devices) which produces two bytes per sample. With the amplifier-ADC combination, the voltage resolution achieved is 0.0244 mV/bit.

The digital part of the implant is the control logic which includes a $2-MHz$ clock for the ADC, counters for the sample interval timing and a state machine implemented in a programmable logic device (PLD). According to the authors, the state-machine architecture has been designed to scale easily to more channels or higher sampling rates than the current 1 kHz.

External part
As seen in Fig.2.20, the implantable unit has five (percutaneous) connections to the backpack: $+5V$ supply voltage, $+2.5V$ virtual voltage, ground, serial-data output and clock. The unipolar reference for the electrodes is connected to this virtual voltage. The clock is only active when there are data on the serial-data line. In the backpack, a custom serial card has been implemented which receives data and sends them to a serial-to-parallel FIFO (of $8192-byte$ size). These data are input to a parallel port of a board that contains a CPU (25-MHz 386SX) and WLAN card (LM3000 Aironet). The CoreModule/386-II (Ampro Computers) was chosen as the computer because of its small size and low power requirements. Communication between the WLAN-card and the computer is achieved through a PCMCIA interface. The computer is responsible for packaging the data, establishing a remote FTP connection to a remote workstation (Sparc 1, SUN Microsystems) through the WLAN-card and forwarding the data for storage. The backpack also includes a battery and two custom DC-DC converters. The first DC-DC circuit is a low-current module used to power the implantable unit. The second one is a high-current unit supplying power to the backpack itself. Finally, on the workstation-end of the system, the authors have developed a utility called TELVIEW for retrieving and visualizing desired data, plotting functions, printing etc..

Communication scheme
As described in the previous sections, communication between parts is required in various parts of the system. The ADC converts analog data to $12-bit$ quantities which it, then, packages as $16-bit$ ones and transmits them serially over a percutaneous cable to the backpack computer (i.e. not wirelessly). The implant state-machine triggers nine conversion sequences (one per channel plus one extra) from the ADC every millisecond, effectively generating a data stream with an average bit rate of $144,000\ bits/sec$. The ninth conversion is ignored by the backpack serial card and is overwritten with a sequence number for signifying the packet start and for performing a data-sequence check. Since the 4 most significant bits of every packet contain no information, they are stripped by the serial card enabling the repackaging of three $16-bit$ samples to only 3 $bytes$, effectively reducing the stream bit rate to $112,000\ bits/sec$. This stream is, then, sent to the FIFO. When the FIFO becomes one quarter full, a hardware interrupt is generated

which causes the backpack CPU to open a file on a remote volume (through the WLAN card) and write data to it. The required bit rate ($112,000\ bits/sec$) is smoothly handled by the WLAN card which uses a $2.4-GHz$ FHSS radio with an indoor range of approx. 150 m at a rate of 1 Mb/sec.

Electromechanical specifications
The implantable unit is a custom PCB with surface-mounted components and measures 73.66 mm $\times$ 57.15 mm. It is mounted inside an implantable defibrillator housing (Guidant Corporation) with dimensions 78.74 mm $\times$ 76.20 mm $\times$ 22.86 mm. A milled custom nylon header has been used to seal the can. Silicone pacing lead headers were used to provide passthroughs for the input lines. For the backpack power, a battery pack consisting of 12 alkaline C-cells and 8 AA-cells has been used. Such a battery pack can provide a system autonomy of over 12 hours before replacement is needed. The implant requires 34 mW (6.8 mA @ 5 V) of power and the backpack 2.5 W while transmitting and 2.1 W otherwise. As seen before, in order to reduce development time, standard commercial parts have been used wherever possible.

Miscellaneous issues
The implantable unit has been placed into three mongrel dogs for periods of 1 to 5 days. Left-coronary-artery occlusion has been performed to the subjects through surgery to make them prone to sudden death arrhythmia. Animals that survived the operation, were returned to the laboratory after 5 days for monitoring. The backpack has been attached to the dogs (in isolation) and implant electrodes have been placed in 5 locations on the epicardium. Signal comparisons between the implantable system and a laboratory 528-channel cardiac mapping system were, according to the authors, indistinguishable. Future improvements of the proposed system include replacing the general-purpose computer used with a custom-designed mC and the commercial WLAN card with a custom transmitter - adequate for shorter distances than the current 1 km- so as to reduce power consumption and, thus, battery size and device lifetime.

2.2.19 A telemetry-instrumentation system for monitoring multiple subcutaneously implanted glucose sensors (Shults et al., 1994) [63]

Application scenario
Initial studies of implantable sensors invariably begin by attempting to percutaneously monitor the sensor, which is a difficult task altogether, especially for periods longer than a few days. One arising problem with percutaneous access is the possibility of infection at the skin puncture point. In the specific area of interest (of this paper), i.e. oxygen or glucose sensors, several attempts of radiotelemetry systems have been attempted to solve this problem resulting in devices with one-two months of operation before discharging.

This paper proposes a new implantable system for wirelessly monitoring implanted glucose sensors which bears several improvements over current implementations. System architecture can support on-the-fly addition/subtraction and coexistence of more than 10 sensory implants in the same area with a typical lifetime of 1.5 years.

General overview
The proposed system has a typical setup. It encompasses an electrochemical sensor for acquiring glucose readings, a low-power CMOS circuit for transmitting data externally and a remote computer with receiver for storage and processing.

Implanted part
The sensor is electrochemical in nature and based on "enzyme electrode" principles. With a standard three-electrode setup the sensor measures a current proportional to glucose concentration. Yet, this quantity is not measured directly but is rather converted to hydrogen-peroxide (H_2O_2) concentration (in the presence of an enzyme). This latter concentration is, then, oxidized at a platinum working electrode set to a $0.6-V$ potential to a silver/silver-chloride reference electrode. This setup along with a block diagram of the overall implant is depicted in Fig.2.21. The amplifiers used are low-power, low-input bias-current CMOS devices. The anode current is processed by a current-to-voltage converter with a sensitivity of 0.1 V/nA. It is important to mention that this portion of the circuitry remains on at all times to protect the working

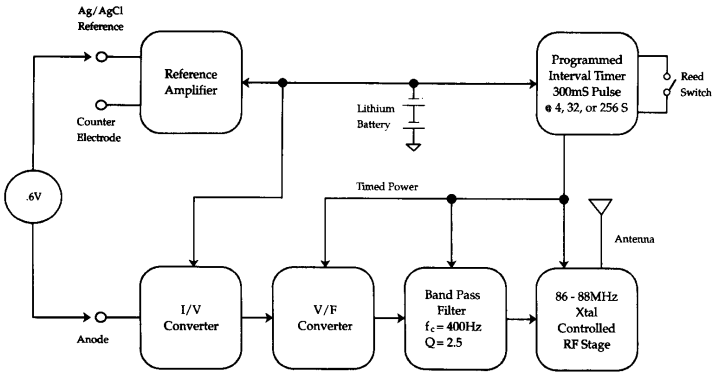

Figure 2.21: *Block diagram of the sensor-transmitter circuit.*

electrode surface from power-up transients and possible accumulation of oxidizable species. Then, the converted voltage signal is inputted in a VCO circuit for conversion to frequency. When the sensor output is equal to zero, the VCO produces a $300 - Hz$ square wave. As the sensor current increases up to 10 nA, the VCO converts this to a $500 - Hz$ square wave. As expected, the VCO is temperature-sensitive with a tempco of $+1.4\%/^oC$. The VCO output is fed to a bandpass filter for removing the DC component and any higher harmonics; the resultant output is a $300 - 500$ Hz sine wave.

The signal biases the RF oscillator circuit and generates both AM and FM modulation. In order to support multiple implants in the same area, RF frequencies are built with crystals of varying resonant frequencies and are hand-picked for each new device. The oscillator tank circuit is comprised of a parallel capacitor/inductor network with the antenna being formed as single-turn printed-circuit loop antenna on the PCB edge and the capacitor being adjustable from 11 to 20 pF to optimize output power and reduce AM distortion. The transmission period and interval between transmissions is adjustable and can selected through a *magnetic reed switch* (by bringing a magnet close to it) which increments an electronic switch. The switch position sets valid transmission intervals of 0, 4, 32 or 256 *sec.*The $0 - sec$ interval serves as a standby mode where transmission is disabled.

External part
The external part of the designed system is a receiver circuit which is connected to decoding circuitry which, in turn, is connected to a computer. The receiver is a programmable scanner (Realistic PRO-2006, Tandy Corp.) which has been modified to allow for remote operation. The connection-cable is $16 - bit$ wide and connects to a custom decoder card residing inside the PC. The receiver can be programmed by the computer with a specific device frequency for reception, with the desired demodulation mode (AM or FM) and, also, with extra timing and handshaking conditions to make command transfer (to the receiver) more robust. If the receiver is tuned in on an active channel, it will acquire the transmitted signal and will send it through a combination of a second-order, low-pass filter and a band-pass filter to further suppress unwanted harmonics. The outputted sine wave will be presented to a comparator whose output is a TTL-level square wave. 16 consequent data square waves are, then, used to gate a $500 - kHz$ counter. Its $8 - bit$, digitized output is stored to the PC disk, which is notified of data availability from appropriate interrupt signals originating in the interface card.

All control and forwarding of data in the card as well as interrupt generation is achieved by software written in Microsoft C and QuickBasic. Additionally, this software is responsible for processing and graphically displaying data, for adding/dropping devices from auditing and for resolving race conditions among overlapping data transmissions from multiple implants.

Communication scheme
As previously mentioned, the implants can modulate data either in AM or in FM. RF oscillator crystals are selected in the range from 86.00 to 87.95 MHz at $50 - kHz$ inter-

vals. This allows up to 40 discrete channels on which information can be simultaneously transmitted. On the receiver end, the custom card can be set to demodulate in each of the two modes and, also, provides equal coverage in time of all monitored channels while resolving device transmission coincidence issues.

Electromechanical specifications
The PCB board dimensions are 2.5 $cm \times 6.3\ cm$ and those of the overall package are 1.2 $cm \times 3.2\ cm \times 7.0\ cm$ whereas its total weight is equal to 27 g. For packaging, a polyethylene outer shell filled with an encapsulant has been used and the complete assembly has been jacketed in surgical-grade, double-velour, polyester fabric to ensure tissue ingrowth and anchoring into the subcutaneous tissue. The power source for the implant is a pair of lithium coin-cells (Panasonic BR2330) with a capacity of 0.25 Ah. The overall power consumption in standby mode is 39.2 μW (7 μA @ 5.6 V) and during transmission 16.8 mW (3 mA @ 5.6 V). With the shortest transmit interval, this projects a lifetime of 45 days. Assuming longest transmit interval for the whole month save for one day where the shortest transmit interval is used, battery lifetime approximately reaches 1.5 years.

Miscellaneous issues
Sensors were usually implanted, two at a time, in mongrel non-diabetic dogs, which were unrestrained after surgical recovery. After acquiring reference values for the sensory data, glucose infusions have been performed to the animals and glucose levels were left to decay. By comparing sensory data with ones acquired by a clinical laboratory, good performance of the system has been displayed.

2.2.20 A wireless implantable electrical stimulator based on two FPGAs (Sawan et al., 1996) [60, 58, 56, 59, 57, 10]

Application scenario
Implantable neuromuscular stimulators have been developed in the past for the treatment of many organ failures. However, effective control of the bladder for complete evacuation has not yet (1996) been achieved due to a complex mechanism which simultaneously produces contraction of the sphincter. Additionally, the authors highlight the lack of significant features in current commercial implementations of stimulators such as wide range of programmable parameters, high-frequency stimulus generation, waveform flexibility (monophasic, biphasic, anodic etc.) and high efficiency in power and data transmission.

For the above-mentioned reasons, the authors are proposing a new passive, single-channel, implantable microstimulator based on FPGA devices and designed for restoration of normal bladder function to paralyzed patients. The implant is externally controlled and powered by a hand-held dedicated controller through a wireless link which is capable of delivering parameterized stimulation patterns, adapted to the patient's needs.

General overview
The complete miniaturized stimulation device is composed of the hand-held external dedicated controller and the implantable stimulator. The inductive link between these elements is a Manchester-coded, AM-modulated signal and will be further discussed later.

Implanted part
A simplified block diagram of the implant is depicted in Fig.2.22. Main building blocks of it are an inductive antenna followed by a rectifier which uses the transmitted RF carrier to power the device, an AC/DC-voltage converter and regulator, an AM demodulator for recovering transmitted data, an FPGA (Actel) chip which is the digital control for the whole implant and a DAC followed by a linear current source for driving the stimulation electrodes.

The FPGA further consists of six components with the task of receiving the encoded data from the analog circuitry and producing a series of amplitude values corresponding to the desired digital

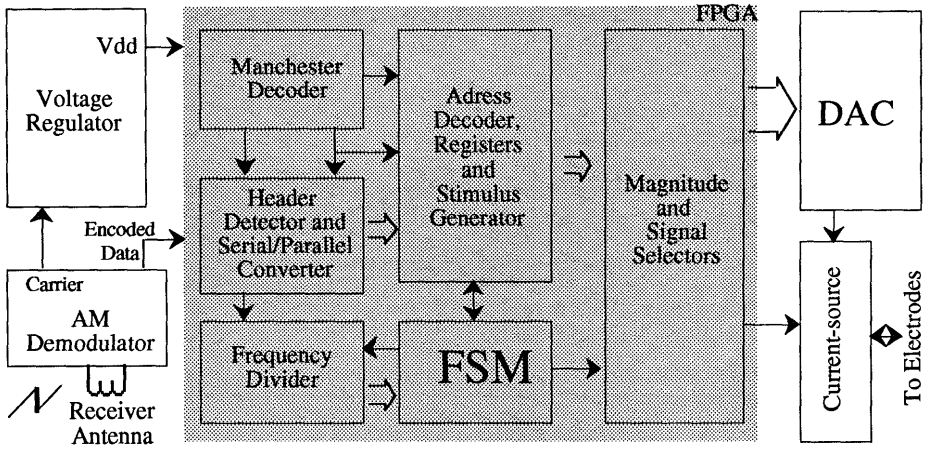

Figure 2.22: *Block diagram of the implant.*

waveform. The first one of those blocks is the *Manchester decoder* which which extracts a clock signal and command data from the received signal. Commands come with a leading $8-bit$ header for avoiding undesired stimulation events from occurring. A *header detector* is utilized for this purpose, which stores the serially-received header into a register for checking. A crucial component of the FPGA is an *FSM* which is assigned the task of synchronizing the data flow among all functional blocks. It receives the synchronous clock ($300-kHz$) and serial commands from the decoder module and converts them into (parallel) $8-bit$ command words. On proper header reception, it stores subsequent parameter data to dedicated registers. Next in the data flow is the *stimulus generator* block which reads the above registers and generates a corresponding output signal. For generating longer and shorter time durations for the various stimulation pulses, an extra module is implemented, a *frequency divider*, which uses two different clocks, a slower and a faster one, respectively. The final component of the FPGA is an *amplitude selector* circuit which delivers one of three possible settings with respect to the digital stimulation waveform: a LF waveform amplitude, a HF waveform amplitude and zero. With these final settings, the stimulus is fed into the DAC and, then, to the electrodes for application.

External part

A block diagram of the Hand-Held External Controller (HHEC) is depicted in Fig.2.23. This module contains all necessary peripherals to create a user-friendly system and allows for full programming of the implant. Four main functional blocks are included. A *user interface* is composed of a 4-button keyboard and a 4x16-character LCD for making selections and previewing preprogrammed stimulus commands that are to be sent to the implant. These preprogrammed commands are stored in an *EPROM* which is divided in two parts. The first part stores data for display purposes in the LCD whereas the second one contains entries with different parameter sets. Each set consists of $9bytes$. As control unit for the HHEC, a second FPGA is used which implements its own FSM for accessing EPROM data, for driving the LCD and for encoding and transmitting the commands. Modulated carrier signals are presented to a class-D amplifier and antenna for transmission. To complete the device, a $300-kHz$ clock on-board circuit as well as a power-on-reset (POR) circuit are added. Programmable parameters of generated stimuli are: a HF-signal of $1-900\ Hz$ modulated by a LF-signal of $1-100\ Hz$, pulse width of both signals of $10-900\ \mu sec$ and maximum

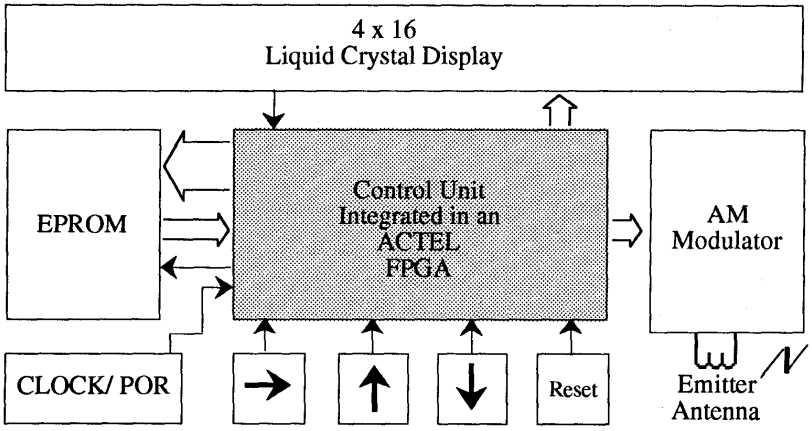

Figure 2.23: *Block diagram of the external controller.*

amplitudes of 3 mA.

Communication scheme
As previously mentioned, the external device AM-modulates a $20 - MHz$ carrier by Manchester-coded, $8 - bit$ words of data and the synchronization clock. Commands are transmitted by inductive coupling between the external and internal parts. A command consists of one header byte and subsequent bytes for the stimulus parameters. Communication of data is one-way, i.e. the implant does not send any information back to the HHEC. The transmission rate of the RF link is 300 $kbits/sec$.

Electromechanical specifications
For the implant, a circular PCB of $3.5-cm$ diameter and double-face SMD components to minimize total dimensions is designed. No power consumption details are given. Please refer also to the following paragraph for additional remarks.

Miscellaneous issues
Over the years, various implementations with different design choices have been given of the above described system (Sawan et al.) and for stimulating different sites of the body - namely, bladder wall (detrusor muscle), pelvic nerves, sacral roots or spinal cord. Nevertheless, in all cases, the general system setup has remained intact: an external, (hand-held or computer-based) controller powering and exchanging data with an internal (i.e. implanted), programmable microstimulator are the basic components. Minor differences also exist in the implementation technology and the physical dimensions of the circuits but the principal functionalities remain the same. In this context, such systems have not been deemed diverse enough to be described separately and they are, therefore, briefly outlined below.

In [58] the implant can generate 8 monopolar (or 4 bipolar), independent stimulating currents, its core consists of a full-custom chip which supervises the overall implant operation and accepts 13-bit commands (3 start bits, 8 data bits, 2 opcode bits) from an external controller for stimulation. The chip virtually is an FSM for coordinating implant functional blocks and a timer. For stimulus-parameter storage, 36 system registers and an $64K \times 32 - byte$, off-chip memory are included. Output stimulus currents have a 5-bit resolution. 3 μm-CMOS technology has been used for fabrication, resulting in a 4.51 $mm \times 4.51$ mm-implant with 12,753 transistors.

For chronic experiments on bladder voiding in dogs, an implantable system has been devised in [56, 59, 57]. 24-bit commands (3 header bits, 21 data bits) have been implemented in this case and, for controlling the implant, a gate-array IC has been used with an operating frequency of 1 MHz. The same number of electrodes as above can be driven with stimuli, however, a 6-bit DAC is used for converting the commands to analog waveforms. In the first version of the system, a computer-based PCB card has been designed for interacting with the implant; yet, a second version has delivered a hand-held external processor for urinary prosthesis (EPUP) since the second system has been primarily used for investigating micturition control. The EPUP programs

the electrode configuration and other various stimulation parameters of the implant. The main parameters are: maximum amplitude of 3 mA; stimuli are composed of a HF-signal of $35 - 500$ Hz modulated by a LF-signal of $1 - 20$ Hz; pulse width controlled by a duty cycle of $10 - 90\%$; sacral nerve stimulation of $1 - 15$ sec and a stimulating duration of $1 - 150$ sec. The fabrication process used is 4 μm CMOS with 2000 gates (for the gate array) and die dimensions of 6 $mm \times 6$ mm, placed on circular hybrid PCB with $2.2 - cm$ diameter. Power consumption here is given to be equal to 8 mW and available stimulation frequencies range from 0 kHz to 4.5 kHz.

In the specific context, [10] is the most recent study to the problem of bladder voiding, experimenting with sacral-roots stimulation. In this implementation both the external, hand-held controller and the implant are based on an FPGA for implementing the needed control logic. Digital stimulation signals (prepared through external commands) pass through a DAC in the output and then through a VI-converter and a current amplifier to generate proper analog current stimuli. These stimuli finally pass through an analog switch array so as to generate fully balanced bipolar waveforms. A cuff electrode has been used for stimulation and has, thus, been wrapped around the sacral nerve. For the implant, the FPGA and all peripheral SMD components have been mounted on a $4 - cm$ circular PCB. A difference with the previous implementation is that the FPGA chip there appears to be a mixed-signal one (since it incorporates an analog output stage with driven current sources) whereas this FPGA chip is digital-only and the analog output stage is a separate block.

2.2.21 An externally powered, multichannel, implantable stimulator-telemeter for control of paralyzed muscle (Smith et al., 1998) [64]

Application scenario
Similar to [60] (as discussed in subsection 2.2.20), presented above, this paper is also involved with the issue of functional neuromuscular stimulation (FNS) applications for providing functionalities such as hand grasp and release in cervical-level spinal-cord injury (SCI), stroke and head injury or standing and walking in thoracic-level SCI, stroke and head injury. The authors are describing a flexible implantable-stimulator and telemetry (IST) system which makes provisions for multiple channels of stimulation, multiple channels of sensor or biopotential-electrode sensing and power and bidirectional data communication between the implant and an external control unit (ECU) over a transcutaneous, inductive RF link.

An original element of this design approach is the fact that the authors are attempting a *generic* approach to the problem of neuromuscular stimulation. They work towards describing and developing a complete set of fundamental modules for a versatile implantable neuroprosthetic system. Thereafter, they are free to choose a subset of only those modules necessary to satisfy the specific application at hand. In order to achieve that, they are proposing an ASIC which can provide control for any potential application-specific instance of the system. Also in this paper, a first implant configuration targeted for restoration of hand function in tetraplegic patients has been implemented and is being discussed.

General overview
The overall system typically consists of the IST and the ECU with communication between them achieved through an RF link. A block diagram of the system with the IST displaying all possible functional elements is depicted in

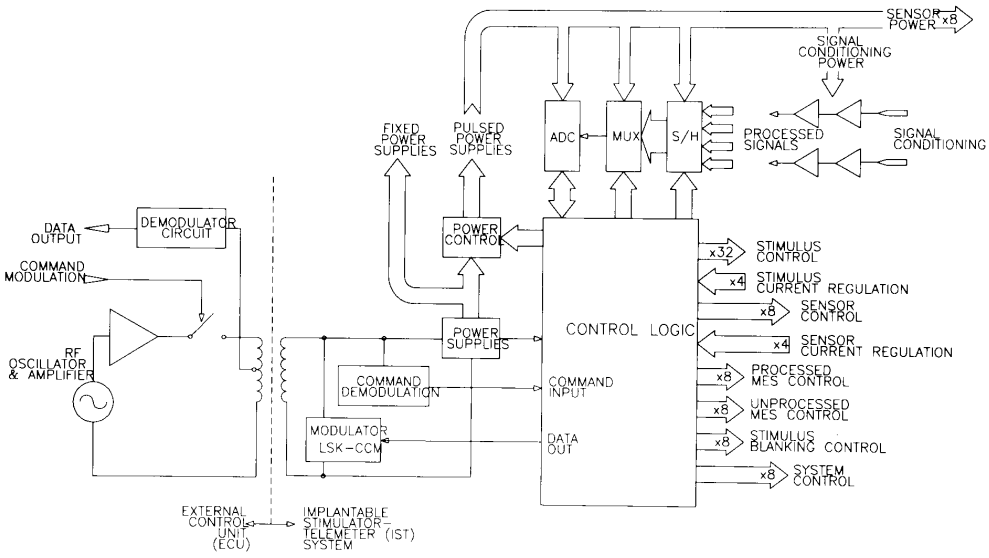

Figure 2.24: *Block diagram of the whole system (with all possible functional modules present).*

Fig.2.24. As seen in the figure, the front end of the external unit consists of transceiver circuitry. For all practical purposes, as host for the external unit, a computer with appropriate analog and digital parts has been used (as discussed later). Besides, similar to the IST, modular, custom implementations of the ECU have also been used and will also be discussed.

Implanted part
The IST is a modular system, composed of functional blocks providing a wide range of stimulus outputs and telemetry channels. More specifically, it can be configured with the following (maximal set of) functions: i) Up to 32 independent channels of stimulation for activation of muscles (or sensory feedback), with independent control of stimulus pulse interval, pulse duration, pulse amplitude, interphase delay (for biphasic stimulus waveform), and recharge phase duration (for biphasic stimulus waveform); ii) Up to 8 independent telemetry channels for sensors, with independent control of sampling rate and pulse powering parameters of the sensor (power amplitude and duration); iii) Up to 8 independent telemetry channels for processed (rectified and integrated) myoelectric signals (MES), with independent control of sampling rate and provisions for stimulus artifact blanking and processing control; iv) Up to 8 independent telemetry channels for unprocessed MES channels, with independent control of sampling rate; v) Up to 8 independent telemetry channels for system functions, providing control or sampling of internal system parameters, such as internal voltage levels.

The implant consists of several functional blocks. As shown in Fig.2.24, the first one is a setup that includes a *coil* (inductively coupled to an external coil) for establishing an RF link to the outside world along with attached *demodulator/modulator circuitry* for receiving commands and transmitting back physiological data, respectively. It also includes appropriate rectification and regulation circuitry for powering the implant from the RF carrier signal. A second block of the implant is the *control-logic circuitry* which is implemented in an ASIC and serves towards decoding and executing recovered commands. It also supervises all other functional blocks and is responsible for formatting data to be telemetered, drives the data-modulating circuit in sync with the commands from the ECU and provides handshake or error reporting back to the ECU as needed. Another block is *multichannel, stimulation circuitry* for generating the stimulus pulses fed to the stimulating electrodes - up to 32 independent channels (see (i) above). There is also a *multichannel, signal-conditioning* block included with circuitry which provides amplification, filtering and processing for acquired processed MES, unprocessed MES or sensor signals - up to 8 independent channels each (see (ii), (iii), (iv) above). A necessary *data-acquisition* block is included for sampling-&-holding and multiplexing of all enabled activated analog channels through a single ADC circuit (presumably with a $12-bit$ resolution). The resulting digital data stream is, then, used to modulate the telemetry link through the control logic. Overall sampling rate is determined by the repetition frequency of the incoming data-acquisition commands. *Power regulation and switching* circuitry for selectively powering the various functional blocks of the implant is included to minimize power consumption of the device. The scheme used is pulse powering of specific circuit blocks in an appropriate sequence, even specific

data channels and sensors. Finally, *system-control* circuitry is present for allowing interrogation and configuration of device operation, e.g. detection of error conditions due to partial or compromised powering or communication across the RF link - up to 8 channels are used by this block (see (v) above).

Proper coordination of the functionalities of the implant is achieved by the - above mentioned - control-logic block. To maintain adequate control processing with minimal circuit size and minimal power consumption, this block has been implemented as an ASIC operating at $1 - MHz$ frequency. However, design constraints such as chip physical size (which includes the number of I/O pads available), circuit complexity and cost have led the authors to a trade-off scheme: They have chosen to separate the command functions as either directly (on-chip) or indirectly (off-chip) controlled capabilities. Directly controlled functions require no circuitry other than the ASIC for full support whereas indirectly controlled ones require additional address demultiplexing external to the ASIC. The obvious disadvantage is the additional circuit area for accommodating them. As a result, the ASIC has direct addressing and control of 12 channels of stimulation, 2 sensors, 2 channels of processed MES and one system command (cf. with maximum functions presented above). Address and control lines were also made available on the ASIC to allow indirect control of omitted functions. Current regulators for the stimulus output stages and sensor-powering circuitry has also been incorporated on chip. The described trade-off has been determined by both the maximum capability of the IST system and the foreseeable clinical requirements.

External part
Two versions of an ECU have been utilized for this system, a laboratory (stationary) controller and a patient-based one. The laboratory controller is a computer-based control and data-acquisition station that is used also for troubleshooting and testing. It consists of a computer with custom analog and digital interface hardware installed. Custom software provides interactive control and data recovery from the implant. The computer generates command control data streams that are used to modulate a function generator and a linear RF amplifier with external RF coil. For data reception from the implant, a second, monitoring coil has been fixed in the field of the external RF coil and demodulation circuitry is used with automatic level detection (for handling various coil displacements). For laboratory test an RF carrier frequency of 6.78 MHz has been selected which has negligible tissue absorption and complies with FCC regulations. The patient-based controller is a dual-processor-based system with rechargeable battery source, RF output amplifier and modulator which allows for control of functions of the implanted devices under patient control. For laboratory use, the portable unit connects to a host computer through a specific interface allowing the clinician to set parameters, retrieve information and control the implant operation. According to the authors, this unit is also of modular construction and can be adapted to several IST implementations (or elsewhere) changing specific circuit boards on it.

Communication scheme
Communication and data manipulation in the IST system, namely "command control

structure" is performed in the ASIC. This structure provides the means by which stimulus, back telemetry and system control are accomplished. The range of possible commands provide flexible external control of the IST *maximum* configuration, as previously outlined. This means, this structure remains the same regardless of the application. Five commands are available and are divided into two basic types: *stimulus control commands* and *data-acquisition control commands*. Each command consists of a digitally coded pulse burst followed by several pulse durations. The coded pulse burst contains 14 *bits* (1 start bit, 1 stop bit, 1 parity bit, 11 command-word bits) and encodes the implant identification code, the function to be performed, the channel address needed for that function and any sensor or stimulus powering amplitude levels needed. It also contains a parity bit for error detection. The number and timing of the pulses that follow depend on the type of command (stimulus or data-acquisition) that was issued and are used by the ECU for achieving communication sync. Since 2 *bits* (of the command word) are reserved for the implant ID, up to 4 uniquely addressable implant devices can coexist under the control of a single ECU. After the command code is transmitted and before the remaining pulses are transmitted, a handshake pulse is expected by the ECU to verify that the implant has correctly received and decoded the command. The remaining pulses give extra information for the operation to be performed. For stimulus commands, pulse width, interphase delay, and recharge duration are specified for the stimulating pulse. For data-acquisition commands, a sensor power-duration pulse is specified followed by up to 4 "empty" pulses wherein the ECU awaits the implant to transmit back sampled data of 14 *bits* (1 start bit, 1 stop bit, 12 command-word bits). Since all channels are independent in function, interleaved commands and overlapping functions may occur. Given the fact that communication is achieved over a single RF link, all commands must time-share it. Also, duration of a command may vary substantially for a few microseconds to several milliseconds. For the above reasons, a limit in the repetition rate of inputted commands is difficult to predict and heavily depends on the application at hand.

As mentioned previously, power and data are transmitted over the inductive link from the ECU to the IST. Command modulation is performed by directly gating the RF carrier on and off (two-level ASK a.k.a. on-off keying). This scheme provides a simple and reliable means of digital data transmission. Back-telemetry from the implant is achieved based on the impedance-reflection principle, encountered also in previous papers (e.g. see subsection 2.2.15). The technique used is termed "load-shift keying using circuit configuration modulation" (LSK-CCM): the implant modulates the load it places on the external transmitter through the existing inductive link resulting in an equivalent modulation of the voltage across the external RF coil. Advantages of the LSK-CCM technique is that it provides powering and bidirectional data over a single pair of RF coils operating at a single frequency. It also eliminates the use of RF-signal generation circuits in the implant and is compatible with the gated RF-carrier technique. Present versions of the scheme support reliable data transfer at rates in excess of 200 $kbits/sec$.

Electromechanical specifications

Due to the generic description of the IST system, no specific figures are given for its

performance. Therefore, in this subsection figures are given for the first prototype system that has been built based on the IST framework. For restoration of hand grasp and release function in individuals with C6 SCI, using wrist position of the stimulated hand as the command signal, a tailored IST in combination with an implantable joint angle transducer (IJAT) has been implemented. The IJAT will properly stimulate sensors of the IST (placed in the radio-carpal joint) which will externalize data to a patient-based ECU which - in turn - will generate stimulus commands and send them back to the IST for delivery to paralyzed muscles. A low-power, $1.2 - \mu m,\ n - well$ CMOS ASIC control with 10 simulation channels (nine for motor stimulation, one as sensory feedback source) and 1 data-acquisition channel. Also, the patient-based ECU is utilized. Due to the number of required components and the complexity involved, a multilayer, thick-film substrate has been used resulting in a circuit size of $2.5\ cm\ \times\ 3.75\ cm$. For packaging purposes, a hermetically sealed titanium (grade-II) capsule with multiple feedthroughs has been selected. The whole capsule (save for the titanium lid which is used as anodic reference for monopolar stimulation) is further encapsulated in medical-grade epoxy. Overall implant power consumption is less than 120 mW, dimensions are $10.0\ cm\ \times\ 4.5\ cm\ \times\ 1.0\ cm$ and the weight is equal to 60 g.

Miscellaneous issues

In vivo testing in a dog model has been performed and results show that them implant has been fully functional for 18 months. Alternative command schemes are investigated by the authors since experimental results have shown noise pick-up by the sensor circuitry due to the existing RF field. This noise is manifest primarily as a small DC offset on the digitized sensor data.

2.2.22 An implantable neuro-stimulator device for a retinal prosthesis (Clements et al., 1999) [12, 13]

Application scenario

The discovery that direct electrical stimulation of retinal neurons in cases of retinus pigmentosa and macular degeneration can create visual sensation in patients has been the incentive for this paper. The authors have designed an electronic prosthesis that bypasses defective eye photoreceptors (rods and cones) and creates images by generating electrical stimuli. They have, therefore, developed a flexible, implantable power/data receiver and stimulator circuit in CMOS technology which can drive a 10×10-array of retinal electrodes with biphasic-current stimulus pulses at real-time visual rates.

General overview

A conceptual illustration of the overall system is depicted in Fig.2.25. Over an inductively driven coil, the device can recover power and data from an external system. This system consists of a camera for capturing frames, encoder and transmitter circuitry for sending them over to the microstimulator.

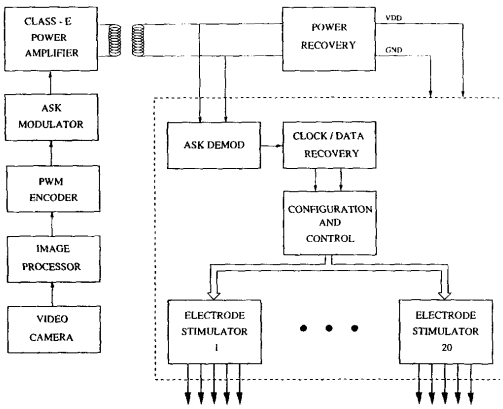

Figure 2.25: *Functional diagram of the retinal prosthesis.*

Implanted part

ASK modulation on a PWM data train is used over the inductive link between the external and the internal part. Rectifying and low-pass filtering circuitry is included in the output of the receiver coil for the implant to recover a DC signal from the carrier and data from the carrier envelope. A comparator circuit is used for detecting the amplitude shifts in the envelope and also implements a voltage hysteresis of 1 V to prevent the creation of false transitions in the PWM output due to noise or residual ripple. The data stream and a clock signal are further extracted from the PWM waveform by a delay-locked loop (DLL) circuit which locks its voltage-controlled delay line to the PWM rising edge. The received data provides visual information for as well as controls the stimulus circuits. In the current implementation of the implant, the ASK demodulator, data recovery, control logic and stimulator circuits for 100 electrodes are all integrated in a single CMOS chip.

The chip incorporates 20 pulse stimulator circuits. Each one of them implements $4-bit$, linear amplitude control and operates in one of three current ranges with full-scale values of 200, 400 and 600 μA and LSB increments of 12.5, 25 and 37.5 μA, respectively. A single range for all 20 stimulators is selected during configuration. Each stimulator circuit is connected to 5 electrodes throughout a demultiplexer. Implemented in conjunction with the output of the demultiplexer is a switched-bridge circuit that allows a single current source to create bipolar pulses (as required for neural stimulation), effectively saving the extra circuit area for implementing two (positive and negative)

current sources. Each stimulator consists of 15 parallel current sources and 4 data bits in each frame switch 8, 4, 2 and 1 sources. Two configuration bits select the bias voltages for one of the three available current ranges (as discussed above).

Apart from the analog part, the chip also contains a digital part which implements a control-logic block. This block creates clock signals that control the distribution of the input data to the drivers, the timing and polarity of the pulses and the sequencing of the demultiplexers. The core of the timing logic is an $80-bit$ ring counter that is clocked by the transmitted-data clock. The timer cycles 5 times for each image frame and, therefore, the resolution available for controlling the timing of the current pulses is 0.25% of the frame period. By initializing the counter state with two blocks of consecutive 1's with particular lengths and positions, we can define the widths and intervals of the positive and negative pulses (for the stimuli). Each demultiplexer is controlled by a 5-stage ring counter which cycles through the 5 electrodes once per frame.

External part
In the external system, a miniature video camera supplies visual information to an FPGA-based image-processing unit. This unit collects, compresses and formats data for the implanted stimulator. It can also be programmed to perform arbitrary image processing algorithms for enhancing the perception of the patient. The unit generates a serial data stream and clock which are encoded as a PWM waveform. The PWM signal is used to ASK-modulate a resonant class-E amplifier that drives the primary coil of the inductively coupled link. The above components are mounted on a pair of glasses to be worn by the patient.

Communication scheme
As discussed above, amplitude modulation is used over the inductive link since it is simple to create in the class-E transmitter and easy to detect in the implant. To minimize data dependencies so that the recovered voltage is as much as possible insensitive to the data content, a type of PWM coding (alternate mark inversion) has been used for controlling the signal amplitude. This PWM waveform has the additional advantage that a rising edge provides the clock. ASK -demodulator and PWM-decoder circuits can operate at data rates from 30 $kbps$ to more than 1 $Mbps$ and the stimulus circuits can operate at up to 500 image frames per second.

Electromechanical specifications
The implant has been implemented in 1.2 μm CMOS technology and the die has a size of 4.6 $mm \times 4.7\ mm$. The maximum power dissipation in the retinal tissue for worst-case image data and pulse widths is 63 mW whereas typical values are in the range of 1 to 3 mW. Power consumption of the IC depends on the image frame rate; for a frame rate of 100 Hz (i.e. data rate of 40 $kbps$) power consumption maximally is equal to 3 mW.

Miscellaneous issues
Future implementations will incorporate also power recovery and more than 100 electrodes on-chip.

2.2.23 Fabrication of CMOS IC for telemetering biological signals from multiple subjects (Park J. et al., 1994) [51]

Application scenario
Similar to other approaches, an implantable biotelemetry system which can process simultaneously multichannel biological signals from one of multiple subjects is being implemented. Such biological signals can, according to the authors, be pressure, temperature, pH, biopotentials, ECG, EMG etc.. The implant can, then, transmit the sampled data to an external host for further manipulation. This is a custom CMOS IC and has been designed with small-size, low-power and continuous-measurement features in mind.

General overview
The multiple-subject biotelemetry system is composed of the implantable device itself and of external modules for transmitting commands to the implant and receiving back telemetry from it. Power to the implant is provided by a small implanted battery. A conceptual block diagram of the system setup is given in Fig.2.26.

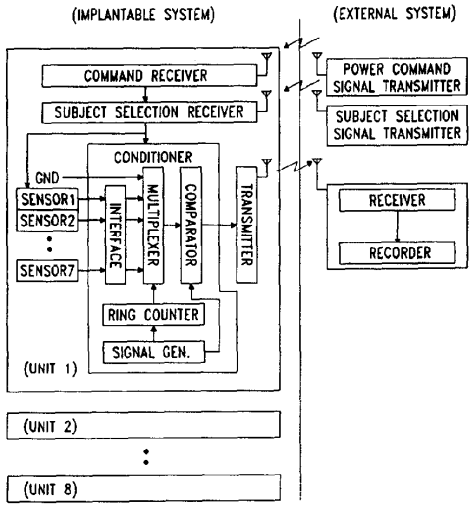

Figure 2.26: *Overview of multichannel telemetry system.*

Implanted part
Up to 8 individual implants can coexist in the same area monitoring up to 8 channels each. For the implant(s) to achieve low-power operation, CMOS technology has been used for its digital components and also a power switching scheme has been implemented for disconnecting the battery when the system is idle. Concisely, the implant consists of a command receiver, a subject-selection receiver, a conditioner and a transmitter.

The function of the *command receiver* is to connect (ON signal) or disconnect (OFF signal) the battery in each implantable telemetry system on demand. In order to keep its power dissipation as low as possible, a pulse-powered circuit has been utilized, which involves intermittent gating of the power supply. After receiving biological data from a specific implant, the external unit transmits an OFF signal back to it which, then, turns power to all sensors and digital circuits off. As a safeguard, battery power is toggled OFF after a constant time interval has elapsed. The *subject-selection receiver* is designed for receiving a subject-selection signal from the external host, selecting a single implant out of 8 implants and then switching the power source ON for it and OFF for the rest of them. On host demand, the power source for the active implant can also be turned OFF. This receiver consists of a serial-in/paralell-out, $7-bit$ shift register which converts the received implant ID and subsequently feeds it to a $7-bit$ comparator. If the regarded implant ID is a match to the received one, then this implant is selected

for data sampling and the rest are turned off. The *conditioner* circuit amplifies and time-multiplexes all 7 measurement channels (plus one reference channel). High-input-impedance, high-gain amplifiers with a gain range of $40-70\ dB$ (depends on the biological signal measured) are used. The signal bandwidth is 500 Hz (i.e. sampling frequency of 1 kHz) which is a sufficient value for most biological signals. The proposed setup considers channel 1 connected to the ground, working as a sync or calibration signal. The next two channels (2 and 3) measure pressure signals. Channels 4 and 5 are for pH and biopotentials measurement, whereas channels 6 and 7 are dedicated to EEG, EKG or EMG acquisition. Finally, channel 8 measures a temperature signal. A *transmitter* is included in the CMOS IC. For achieving low-power transmission, double modulation is used. The (serialized) multiplexer output is directed into a comparator which PWM-modulates the signal by using the triangular-wave output of a signal generator circuit. This signal generator also provides a clock for all digital parts of the design. The PWM waveform is further FSK-modulated (at 80 MHz) and transmitted over the air to the external host.

External part
For development of the external system, a commercial CMOS IC has been used. The system consists of a command signal transmitter, a subject-selection transmitter and a receiver. The latter is assembled by a commercial FM tuner and PWM demodulation circuit.

Communication scheme
Commands signals from the external host are properly set pulses for on/off switching and selecting of implants. More specifically, the subject-selection command signal is composed of a missing-pulse code. This means that a train of 7 or less pulses is transmitted, with the missing pulses in the train specifying the implant the host wishes to address. Back telemetry from the implants to the outside environment is achieved by PWM data which are also FSK-modulated.

Electromechanical specifications
An experimental 1.5 μm, 4 $mm \times 4\ mm$ CMOS IC has been developed for prototyping purposes by the authors. Power figures are not explicitly given in the paper save for the power requirements of the channel amplifiers. By incurring these elements alone, a lower bound of 498 mW to power consumption is given.

2.2.24 Intraocular vision aid (IOS): Optical signal transmission and image generation (Prämaßing et al., 2000) [53]

Application scenario
Implants designed to provide artificial vision to blind people are, these days, receiving more and more attention. Cases of outer-retinal diseases, for instance retinis pigmentosa, have been previously discussed (see subsection 2.2.22). In this paper, the authors have devised an implantable system for repairing blindness due to blurred cornea. This system consists of an external camera wirelessly transmitting digital data to an intraocular CMOS chip which drives a LED display projected on (and, thus, stimulating) the retina.

General overview
The overall system consists of a camera that sends images to a DSP for encoding and, then, to an optical transmitter which, in essence, is an IR LED. The implant consists of a photodiode and recovery circuitry for data and clock signals and a DSP for providing suitable signals to the actual silicon driver and LED display. For powering up the implant, power is transmitted over a (separate) RF link. A conceptual overview of the intraocular aid is given in Fig.2.27.

Implanted part
Over the optical link, the implant receives Manchester-encoded data from the external system and recovers a data train from it. A clock signal is also extracted from the data signal by using a fully integrated phase-lock loop (PLL). The PLL consists of a phase detector, a charge pump, a voltage-controlled oscillator (VCO) and a divide-by-2 circuit. This means that the clock has double the rate (2 $Mbps$) of the transmitted data (1 $Mbps$). No explicit information is given regarding powering the implant or the circuitry used. The LED display is a 32×32-element, micromachined device which is flip-chip bonded to a silicon CMOS driver circuit. Due to this bonding process, light is emitted from the back of the LED-display substrate where microlenses are integrated. The DSP (no information are given), processes the serial data stream containing the camera image and restores it by properly turning LEDs on in the miniature display (through the driver circuitry). This image is, then, reflected on the retina thus transmitting optical signals via the ganglion cell layer and the optical nerve to the visual cortex of the brain. No information is given on the DSP used for controlling the driver of the silicon LED display.

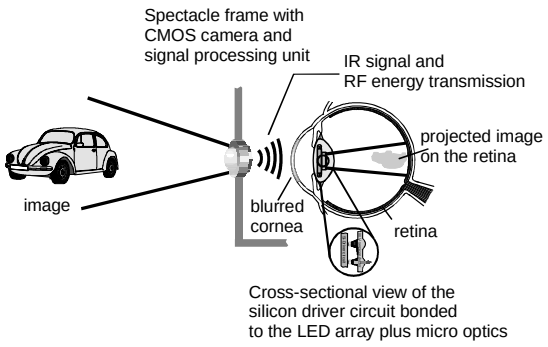

Figure 2.27: *Overview of IOS system.*

External part
Few information is given about the external system. The camera used is a high-dynamic-range CMOS camera which generates a digital, black and white image which is converted

by a DSP into Manchester-coded data signals. Due to strong optical absorption in the cornea, power irradiation to the implant over the same data link would lead to high temperature rise in the eye; therefore, necessary power is transferred using a separate RF link. To avoid this problem also in the optical data link, an infrared LED is selected with a wavelength corresponding to the absorption minimum of the blurred cornea.

Communication scheme
As discussed above, data are Manchester-coded before transmission over an optical link between a LED and a photoreceptor. The supported data rate is equal to 1 $Mbps$.

Electromechanical specifications
The LED display has been fabricated in GaAsP/GaP technology (GaP is the transparent substrate). For the driver, 0.6 μm, n-well CMOS technology has been used and the overall power consumption of the implant is 395 mW (@ 3.3 V).

2.2.25 Neuromorphic cochlea implants (Lande et al., 2000) [36]

Application scenario
Cochlea implants (CI) are a case of most successful electronic systems that interface directly with the human nervous system. Even so, a close look at these systems reveals several non-trivial signal processing tasks and wireless-transmission schemes for signaling to the implanted electronics. Therein a trade-off exists between a limited power budget and quality of required signal processing.

In this paper a novel approach to cochlea implants is devised which relies on known biological models. The proposed system is an analog computational system which can be implemented in single-chip, CMOS technology resulting in small-size and low-power form factors. Additionally, the design nature of such a device will allow for scalability to more audio channels etc..

General overview
This paper conceptually presents and elaborates on a new technique which combines attributes from different approaches and also from bio-inspired models. As such, no consideration exists for potential external systems with specific communication to the implant.

Implanted part
The proposed implant is termed "neuromorphic cochlea implant" and its architecture is based on the combination of two applied techniques. The former is called *silicon cochlea* (SC) and - in virtue - is an analog neuromorphic model of the *basilar membrane* inside the ear. The SC uses micropower CMOS circuits to realize a complete membrane model with minimal power consumption (microwatts). The fluid-mechanical system of the cochlea is modeled as a long cascaded filter structure of more than 100 filter stages. Each such filter stage is slightly resonant and has a different cut-off frequency (CF) with the highest CF early in the cascade. The CF is logarithmically reduced towards the end.

In every stage, the (so far) filtered signal is also output to a separate channel which can then be driven to a separate stimulating electrode. Implementing analog CMOS circuits of such long structures with filters, which are robust and also insensitive to mismatch errors, is difficult; yet, it is achievable (as shown by other researchers) by tuning each stage with a minor resonance (small Q factor) and good stability margin. The described SCs can be used as front-ends for DSP units in cochlea implants. Nonetheless, the authors are proposing a *neuromorphic signal-processing unit* avoiding DSPs altogether. Such a unit mimics the way signal coding is achieved in the human body which is based on spike-shaped signals. This is the latter technique the authors call upon. In short, the number of spikes per second is proportional to the temporal derivative (d/dt) of the analog value to be transmitted. An important property of this coding scheme is the insensitivity to "stuck-at" faults. Also, redundancy is achieved in biological systems by having several neurons encode similar information in several parallel nerves.

With these features in mind and, by combining both techniques, the authors have extended the SC with neuromorphic signal processing (as this spike-based processing is called) to a design implementable in CMOS technology. The structure of this design is depicted in Fig.2.28. In the bottom part, the cascaded-filter structure is shown, each channel equipped with a HP-filter. In combination with the LF-property of the whole cascade (i.e. by superposition of ever-lowering CFs), each channel corresponds to a frequency band. Then, as is done in the Organ-of-Corti (in normal-working ears), a rectification is done followed by an encoding of the signal to a pulse train. The phase-lag introduced with the specific filter setup is - in fact - desired trait of the system since i) it reduces the probability of simultaneous activation of multiple electrode stimuli, and ii) it resembles closely the behavior of its biological counterpart. This is considered very important since research has shown that the phase change in the biological cochlea may also carry useful information (apart from the actual audio signal).

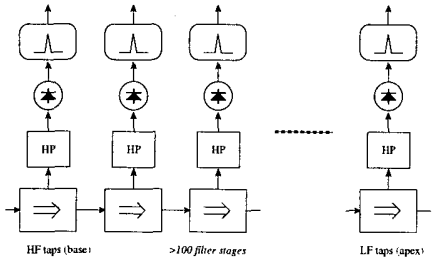

Figure 2.28: *Neuromorphic Silicon Cochlea.*

With the above described system, given a cascade of more than 100 filters, a 10-fold more channels than required are provided for a case of 10 stimulating electrodes. Since the generated spikes are discrete in value, a digitally-controlled, spike-routing switch may be implemented as a digital cross-switch routing network (see Fig.2.29). The signals required may then be achieved through routing of a selected group of channels from the neuromorphic cochlea to the assigned electrode. To make the overall system adaptable to different

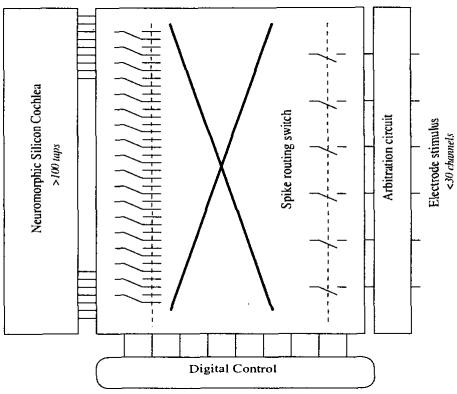

Figure 2.29: *Spike-routing switch (for spike-domain signal processing).*

patients, functions such as selective amplification of each frequency band and adjustment of the frequency band mapped to each channel, need to be obtained. *Gain adjustment* is achievable simply by the number of channels routed together to the same electrode. Since there are roughly 10 channels for each electrode, we may obtain a gain adjustment of up to 10. This is possible because neuromorphic coding is additive in nature. If finer adjustment or better dynamics are needed, more channels may be added. *Frequency band mapping*, on the other hand, is achievable by selecting the group of channels routed to each electrode. A wider frequency band is obtained by routing together channels that are further apart while a small number of neighboring channels will map a narrower frequency band.

External part
Not available (see subsection "General overview").

Communication scheme
Not available (see subsection "General overview").

Electromechanical specifications
The simplification in electronics the described system represents is beneficiary for the final area and power consumption of the CMOS IC. Concurrent research has placed an upper bound of 0.5 mW to the power consumption of a silicon cochlea implant with 117 channels; which is more than 20 to 100 times less power-consuming than a conventional implant. By substituting the DSP component by spike-based processing, a resulting neuromorphic cochlea implant will have an even lower consumption and a total number of approximately 3000 transistors and latches.

Miscellaneous issues
A final important feature of this system is its scalability. Increase in the number of channels or higher electrode stimulation rates are currently pursued by cochlea implant vendors, a trend which leads to disproportional higher power consumption. The authors claim that this is not the case for the neuromorphic implant since no global clock or DSP circuitry is present.

2.2.26 Implantation of a refillable glucose monitoring-telemetry device (Atanasov et al., 1997) [5, 4, 9]

Application scenario

A substantial amount of research effort has been focused in the area of glucose sensing, aimed at fulfilling the need for an implantable glucose sensor to close the loop for an insulin pump, and obtain a complete artificial pancreas. Development of the implantable insulin pump is at a very advanced stage; however, a continuously functioning implantable glucose sensor with long-term stability has not yet been achieved. One type of researched implantable glucose sensors are *biosensors*. Glucose biosensors are generally based on the enzyme glucose oxidase (GOD) which catalyzes the oxidation of β-D-glucose by molecular oxygen producing gluconolactone and hydrogen peroxide. Either the increase in hydrogen peroxide (H_2O_2) concentration or the decrease in oxygen (O_2) concentration due to this reaction can be detected electrochemically (and measure amperometrically), both being proportional to the glucose concentration.

In this context, the authors are proposing a new implantable device with glucose-biosensing and RF-telemetry capabilities for remote data collection and performance evaluation. A special attribute of the final version of the device is its ability to be (percutaneously) refilled *in situ* with fresh enzyme which deactivates over time under the effects of the surrounding biological tissue and is, currently, a primary limiting factor in biosensor lifetime.

General overview

Figure 2.30 illustrates a schematic view of the glucose monitoring and telemetry system. This implant is designed to transmit FM-modulated data to an external personal computer for comparison of blood glucose levels as provided by the implant and by conventional (external) electrochemical equipment.

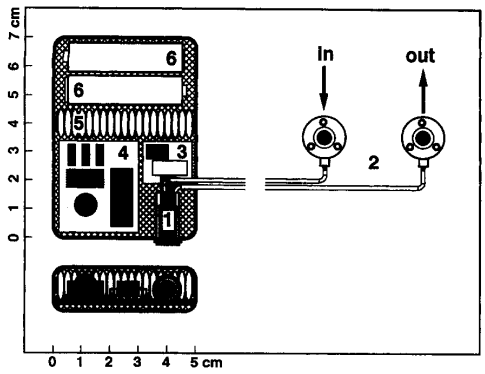

Figure 2.30: *Schematic view of glucose-monitoring and telemetry system.*

Implanted part

The circuit setup of the implant is rather simple. A fully analog circuit is built using off-the-shelf electronic parts, all assembled on a PCB. As shown in Fig.2.30, the implant includes the biosensor (1), silicone capillary refilling tubes with subcutaneous access ports (2), a miniature potentiostat (3), a frequency modulator with a low-power FM transmitter (4), a transmitting coil antenna (5) and the power supply (6), consisting of two AA-size, lithium/thionil chloride batteries. The circuit schematic of the implant can be seen in Fig.2.31.

The glucose biosensor is a three-electrode amperometric device. It employs enzyme-catalyzed oxidization of glucose and is based on the hydrogen-peroxide measuring

principle. The glucose biosensor consists of two parts: an amperometric electrode system and a GOD micro-bioreactor. For the first part, the three-electrode setup used in subsection 2.2.19 is also found here. This three-electrode amperometric system is directly inserted in the sensor housing which is filled with the enzyme[5], thus serving as a micro-bioreactor. Two capillary plastic tubes, the inlet recharge tube and exhaust discharge tube, are used for replacing spent enzyme from the micro-bioreactor, without sensor disassembly. Refilling of the sensor is achieved using two septa via these tubes: one for injecting a fresh enzyme suspension, another for exhausting the spent enzyme.

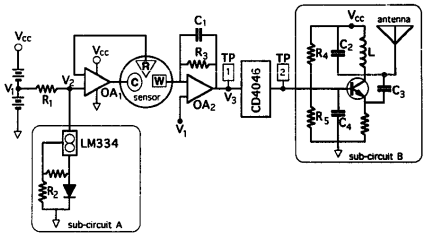

Figure 2.31: *Circuit schematic of the implant.*

The potentiostat employs an IC current source (LM334) to produce a bias of 0.6 V for powering the sensor and converts the current produced in the sensor to a usable output signal. The biosensor produces a current in the range $1\ nA - 17.5\ \mu A$ that is proportional to the glucose concentration in the range $0.1\ mM - 30\ mM$. The current is converted to a voltage by a CMOS op-amp (ICL7642, Harris) which has high input impedance, low bias current ($<\ 1\ nA$) and low power consumption ($<\ 30\ \mu W$). A micropower PLL IC (CD4046) is used as a voltage-to-frequency converter. It converts the voltage signal to a square wave whose frequency is proportional to the voltage. This frequency is then applied to the FM radio transmitter. A commercially available transmitter (Ramsey model FM-5) was chosen due to its small size and low power consumption. Various arrangements of long wire and coil antennae were considered for the transmitting antenna. A small coil antenna incorporated in the unit body was selected with regard to space considerations and to avoiding direct contact of the antenna with the aqueous environment, with consequent heavy loading and instability of the transmitter.

External part

The external-system is primarily used for testing the implant functionality and consists, first, of an FM receiver (ICOM model ICR7000) for detecting and demodulating the FM signal. The tests were carried out with a wire receiving antenna (approximately 6 m long). The receiving antenna is coiled around the operating table (for acute in vivo tests) and around the animal cage during the chronic implantation (in mongrel dogs). Then, the output from the receiver is connected to a shaper circuit and counter board in an IBM-386 personal computer (PROLOG, BusBox). Data are recorded by the computer at time intervals of 20 *sec*.

Communication scheme

FM signaling is used for communication in the telemetry system. As discussed previously, communication is unidirectional from the implant to the external computer system and the $88 - 108\ MHz$ commercial band is used.

[5]To minimize the instability and, thus, the deactivation rate of the enzyme inside the housing, the enzyme has been immobilized by appropriate reagents (inert carbon powder).

Electromechanical specifications
Commercially available, integrated, low-power chips have been used for this system by mounting on a PCB board. The circuit and biosensor were packaged in Silastic (Silgard 186, silicone elastomer, Dow Coming, Midland, MI). The overall dimensions are 5.0 cm $\times$ 7.5 cm $\times$ 1.5 cm and weighs 140 g. Silastic covers the entire system, except the glucose diffusion membrane of the biosensor and the capillary refilling tubes. The system was operated in a mode of continuous transmission suitable for short-term experiments. In the long-term operation mode the transmitter was powered up every 4 min for 20 sec to conserve power, using a built-in micropower timer. No implant overall power consumption is discussed in this paper.

Miscellaneous issues
In order to confirm the proper operation of the implantable glucose-sensor, the wirelessly transmitted data were compared with parallel measurements by conventional electrochemical equipment. Bioanalytical Systems (CV-1) potentiostats and Houston Instruments (1000 Series) recorders were used for data processing and results from in-vitro and acute in-vivo tests show good sensor performance.

A primary advantage of this system is the biosensor refilling process, consisting of access septa for injecting fresh immobilized enzyme into the sensor with concurrent removal of spent enzyme. Moreover, it can be redesigned and automated approximating the refilling of the implantable insulin delivery systems (by using syringe micropumps). This will allow for extending the number of recharge cycles, thus prolonging biosensor lifetime. A secondary benefit stemming from the first one is the highly reliable sterilization techniques (such as autoclaving - i.e. steam under pressure) are now possible due to the refilling technique now possible. The limiting factor in using such techniques before, was the destruction of the enzyme layer in the biosensor. However, in the proposed system the biosensor can be activated after the sterilization procedure by refilling the bioreactor with fresh enzyme material.

2.2.27 An implantable radio-telemetry system for remote monitoring of heart rate and deep body temperature in poultry (Kettlewell et al., 1997) [35]

Application scenario

Livestock remote monitoring is considered in this paper. This is considered an important issue to solve since studies have shown that animals in transit may undergo physiological stress and other symptoms. Such studies have been performed upon environmental monitoring and retrospective analysis of biological samples obtained before and after the journey, thus, not allowing for consistent observations and conclusions to be drawn. Continuous radiotelemetric monitoring of the appropriate physiological variables would greatly benefit such studies.

For this reason, the authors have devised a multichannel, radiotelemetry package for the continuous monitoring of ECG, deep-body temperature and respiratory movements and preliminary tests of a prototype device have been performed in poultry. Active consideration of design issues such as package size and weight, robust construction, large transmission range and low power consumption has taken place. Also, the authors have actively sought to deliver a device compliant with current (1997) regulations and specifications defined by the Department of Trade and Industry (DTI, UK).

General overview

The overall system consists of the poultry implant and further external components for conditioning, processing, display and storage of the received physiological data. Communication between the internal and external components is achieved through FM modulation of data.

Implanted part

It is important to stress at this point that the actual implant is not an integrated chip and/or micromachined device but, rather a package of components, for which the authors are not giving very explicit information. Nonetheless, this paper has been included in the survey for presenting the specific concepts of physiological-data conditioning and transmission used, as described below. In Fig.2.32 a block diagram of the implant is given. No extra processing is performed on the data inside the implant save for the required signal-modulating operations for wireless transmission, which have been specially picked to minimize the size of the implant. The temperature channel receives data from a thermistor sensor (Betatherm 23 K 3 D 300) with an accuracy of

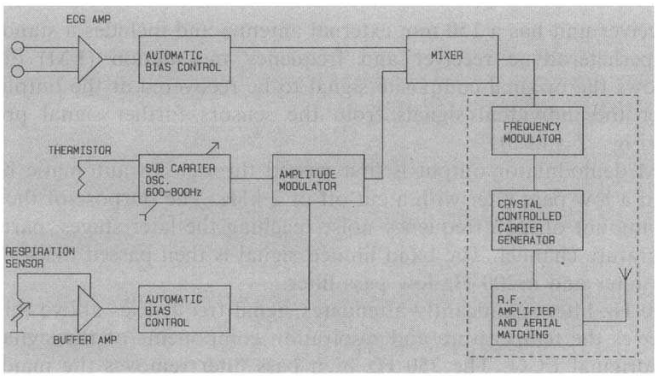

Figure 2.32: *Block diagram of implant circuitry.*

0.3^oC. This channel alone uses a sub-carrier oscillator which is frequency-modulated by the thermistor output. The second channel carries a (bipolar) ECG signal from two Ag, loop electrodes and is being fed to an amplifier and, then, to an automatic bias-compensation circuit. Although not employed in the present study, a third channel has been incorporated into the design of the system to allow measurement of respiratory movements and is also fed to an automatic bias-compensation circuit after conditioning. As seen in Fig.2.32, the signal from the respiratory sensor is superimposed upon the temperature signal by amplitude modulation and, then, mixed with the ECG signal. With the temperature modulation signal occupying the range $600 - 1000\ Hz$, there is a sufficient frequency band below $600\ Hz$ to accommodate the $200 - Hz$ bandwidth required for the ECG signal. As a sub-carrier oscillator was not used for the ECG signal, the $0.1 - 200\ Hz$ frequency band of the ECG signal was directly mixed with the temperature and respiration signals at the mixer stage. The composite signal at the mixer output is, then, used to frequency-modulate the carrier operating at one of the 12 allocated bands within the $173.20 - 173.35\ MHz$ range specified by the DTI. The RF-transmitter consists of a Colpitts oscillator with its oscillating frequency controlled by the composite signal voltages derived from the sensors. Amplitude components of the composite signal modify the amount of RF-carrier frequency deviation and frequency components of the signal modify the rate at which the carrier frequency deviation takes place. The modulated RF carrier is fed to a wire antenna.

External part

FM physiological signals are received externally by a tuned superheterodyne receiver and FM demodulator which allows the original composite signal to be recovered at the output. In order to recover the individual signals from the sensors, further signal processing is required (Fig.2.33). The FM demodulator output is first passed through an automatic bias-compensation circuit and a low-pass filter with a cut-off frequency of $2\ kHz$. The purpose of the latter is to limit the amount of high frequency noise reaching the later stages, particularly on the temperature channel. The band-limited signal is then passed through a $750\ Hz$ high pass filter and a $200\ Hz$ low-pass filter. The $200 - Hz$ filter significantly attenuates signal frequencies above this limit and thus removes the temperature and respiration components of the signal to reproduce the original ECG. The $750 - Hz$ high-pass filter removes the majority of the EGG signal content before the signal is passed to a frequency-to-voltage converter and an amplitude-detection circuit. The latter extracts the amplitude variations of the temperature carrier and, by filtering out the carrier with a low-pass filter, the respiration signal is recovered. The output from

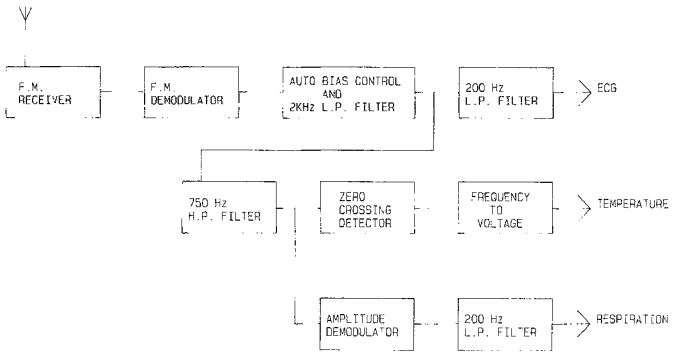

Figure 2.33: *Block diagram of external receiver circuitry.*

the $750 - Hz$ high-pass filter is also fed to a comparator circuit such that the zero crossings of the temperature carrier are detected and converted to square waves. The square wave is fed into a charge balance frequency-to-voltage converter whose output gives a DC voltage proportional to temperature.

The output voltages from the receiver and signal-conditioning units are fed to a computer-based, online display and recording system. Input signals are passed to the computer (Viglen 386, 4 MB RAM, 16 MHz) via an A/D interface (Amplicon, 16-channel, 12-bit converter). Custom written software, including a parameter file for each transmitter and a full calibration of each signal, generates calculated values of each physiological variable for storage on disk and continuous plotting. Sampling frequency and integration or averaging periods is set independently for each input for different applications.

Communication scheme
Superimposed, analog data from three channels are FM modulated and transmitted from the telemetry implant to an external system for further handling. In the current implementation of the system, each receiver is matched to two transmitters with frequency separations of 100 kHz.

Electromechanical specifications
The dimensions of the implant package are 66 $mm \times 25mm \times 29$ mm and it weighs 105 g. A battery has been included in the implant for providing power but no further information on it or the overall power needs of the device are given.

Miscellaneous issues
Experimental results performed by subjecting chickens to thermal stress and measuring physiological data have given good results. Also, post-mortem histological examination of the implantation site showed little sign of an acute inflammatory response, scar-tissue formation or overt injury or haemorrhage.

2.2.28 Subminiature implantable potentiostat and modified commercial telemetry device for remote glucose monitoring (Beach et al., 1999) [6, 7]

Application scenario

Another approach to remote glucose-monitoring implants is given in this paper similar, for instance, to the one presented in subsection 2.2.26, previously. The authors describe a total system but emphasize on the potentiostat circuitry which is required for glucose-sensor biasing and on the telemetry unit which is a modified, commercially available digital transmission unit. This first version of the developed system is a subminiature, PCB-mounted assembly of commercial components, also. Still, the authors are readily proposing a next-version implantable module with smaller dimensions, currently under development.

General overview

The overall system consists of the subminiature implant and of an external computer-based system which communicates wirelessly with the implant. Glucose-level measurements are telemetered using digital modulating/demodulating circuitry (On-Off Keying, OOK). A graphical illustration of the overall setup is given in Fig.2.34.

Implanted part

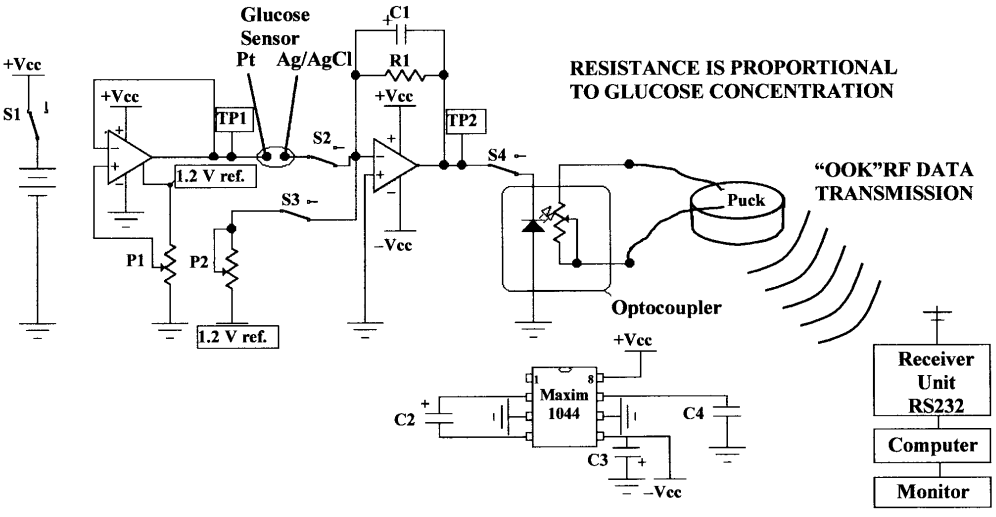

Figure 2.34: *Circuit schematic of implant and external setup.*

The implant consists of an *amperometric glucose sensor*, a *potentiostat*, an *optocoupler* and an off-the-shelf *telemetry device*. The glucose sensor, is a miniaturized biosensor based on glucose oxidase and utilizing a two-electrode design: a glucose-indicating (working) Pt electrode and a Ag/AgCl refrence/counter electrode. It can yield current proportional to glucose concentrations in the range 1 nA to 2000 nA. The potentiostat implements an adjustable bias voltage (P1) for powering the sensor. The telemetry device used here is a modified version of a telemetry unit (Ambulatory Monitoring Inc., AMI) initially developed for temperature monitoring (through a thermistor). Inside the device are included all required circuitry elements

like power supply, op-amps, microprocessors, radio-transmitter etc.. Additionally, this device has sleep and active modes, and allows for programmable transmission intervals from 5 *sec* to 10 *min*. The authors have modified such a unit for use with the implantable glucose sensor by utilizing an optocoupler and new circuitry for the sensor voltage source.

To implement the potentiostat while at the same time keeping implant size minimal, a micropower, CMOS op-amp chip (Maxim MAX951) of micromax size (i.e. 80% of SMT size) with low-bias-current and high-input-impedance characteristics has been utilized. A voltage converter (Maxim MAX1044) converts to the required voltage levels for the system from an included $3.7 - V$ DC, lithium battery. The Pt electrode of the glucose sensor connects to the (MAX951) op-amp output at the TP1 location for a $+0.7 - V$ DC bias voltage and the Ag/AgCl electrode at the S2 location. A transimpedance amplifier (second MAX951 chip) converts the sensor-generated current to an output voltage. This voltage component (S2) is added to a biasing-current-offset voltage component (S3), amplified and used to drive the optocoupler (S4) in the desired voltage range. As sensor voltage varies due to the glucose concentration, the optocoupler output resistance changes. This resistance is connected to the telemetry device (referred to as "puck" due to its hockey-puck shape), which converts resistance to a digital value within its included mP. Then, the puck transmits the digital resistance value by OOK-modulating its transmitter carrier frequency and sending a digital serial data transmission stream to an external receiver via its internal antenna. In this paper, transmissions are set to utilize the frequency of 303.825 MHz. The optocoupler (VTL5C2 EG&G Vactec) is a module with a LED and photoresistor. Care has been taken to ensure the transmitted resistance values are within the representation range of the puck which digitizes its input and transmits an output of $64 - K$ digital counts.

External part
Externally an antenna and receiver module, which has also been provided by AMI, are used. The receiver demodulates the digitally based serial data and sends it to a computer using the RS232 protocol. Accompanying software has also been modified to activate, deactivate or set a new transmission interval for the puck and also for on-screen readout or data logging to disk. Apart from the glucose-concentration data, puck transmissions also include diagnostic and other information in the data stream. Finally, the system can support 40 different pucks simultaneously.

Communication scheme
For communication the On-Off-Keying scheme has been used which is the digital modulation technique also known as Binary Amplitude-Shift Keying. The OOK technique conserves battery life, as opposed to using continuous FM (as seen, for instance, in subsection 2.2.27). Transmissions utilize a frequency of 303.825 MHz.

Electromechanical specifications
The dimensions of the PCB (including SMT components) which was designed for the implant are 16 mm $\times$ 18 mm $\times$ 7 mm. Power is provided by an AA-size, 3.7 V, lithium-thionyl-chloride battery of 2200 mAh capacity. The puck is cylindrical, 26 mm

in diameter and 9 mm high, and is powered by its own, internal, CR2025 $LiMnO_2$ battery. It can operate for 3 months at $5-sec$ transmission intervals and for a year with $10-min$ intervals. The potentiostat-optocoupler combination, on the other hand, for an average sensor output current of 1000 nA requires 1124.8 μW (304 μA @ 3.7 V) of power, resulting in approximately 300 days of lifetime. Therefore, the authors estimate a lifetime of more than a year for the overall implant, with an AA battery (2200 mAh) at less than 1000 nA current. By utilizing an external 1/2-AA battery, the implant package overall envelope will be 18 mm $\times$ 26 mm $\times$ 40 mm.

Miscellaneous issues
In-vitro testing of the subminiature device has given very good results, which are correlating closely to standard potentiostat calibrations.

2.2.29 A dedicated microprocessor for externally powered implantable pain controller (Wei et al., 1997) [70]

Application scenario
Based on the Control Theory of Pain, spinal-cord stimulation (a.k.a. dorsal-column stimulation) involves the selective recruitment by electrical stimulation of low-threshold, large-diameter nerve fibers, collateral in the dorsal columns of the spinal cord to inhibit or block transmission of pain signals to the brain. Wei et al. present in this paper a dedicated mP which can fully drive up to 8 channels simultaneously by delivering programmable monophasic, biphasic or mixed-mode stimuli to nerve tissue. The overall implant is a mixed-signal CMOS ASIC which receives power and data from an external source.

General overview
The internal structure and functionality of the microstimulator implant is delineated in this paper. Power for the implant, as well as the electrode-stimulating instructions to be followed, are supplied by an external processor which transdermally transmits AM-modulated, Manchester-coded commands. A simplified diagram of the IC is given in Fig.2.35.

Implanted part
The implant consists of digital and analog parts. The digital component is the dedicated mP (termed ICASHPAN) performing logic control on the whole implant - i.e. command decoding and channel manipulation. The analog component is further broken down into an AM demodulator and an AC/DC-converter for extracting data and power components from the received signal, respectively, and an output stage which contains 8 identical channel

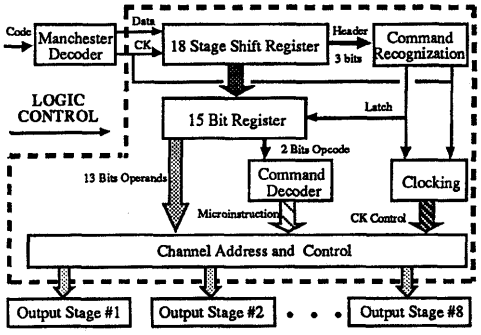

Figure 2.35: *Conceptual diagram of the processor chip.*

circuits, all digitally controlled by the ICASHPAN.

The AM demodulator extracts the Manchester-coded envelope from the RF carrier signal and sends it to the Manchester decoder for data extraction. The AC/DC-converter also receives the carrier and converts it to a DC voltage for powering the mP. $15-bit$ commands and a clock signal are supplied by the transmitted Manchester code. Commands are stored in a data register and undergo decoding by the mP. They include an address field for selecting a specific channel and a parameter field for it, regarding stimulating-current amplitude, polarity etc.. The design allows for electrodes in ground mode, high-impedance mode, two polarities (source or sink mode) or one of 32 discrete amplitudes. Through provided commands, stimulation can start and stop simultaneously or individually for all 8 channels. The duration and monophasic or biphasic nature of the stimuli is specified at a very low-level by the supplied mP commands. For instance, to achieve biphasic operation, two electrodes are to be programmed with specific amplitudes and opposite polarities which alternate at a rate equal to the issue rate of a polarity-toggle command (namely, TURN) by the external processor.

The output stage of the implant consists of 8 digitally controlled analog circuits. Each one further consists of two groups of current sources (source and sink) with values I, 2I, 4I and 8I to build the 32 discrete current-amplitude values. Each pair of current sources is controlled by a switch which connects or disconnects it from the channel output. Maximum current intensity I is adjusted by an external trim-resistor at manufacture time. To achieve *charge balance* and, thus, avoid charge accumulation in the stimulated tissue, biphasic pulses should be used. Due to device mismatch, this cannot always be ensured; therefore, an extra switch is included in the channels for grounding the current sources on issue of a special command to the mP. Also, an in-series capacitor has been included in the channel to safely block any DC current component from passing to the living tissue.

External part
Information given about the external system is limited to a processor which includes a Manchester-format command generator and an AM-carrier transmitter.

Communication scheme
Communication between the external processor and the implant is achieved through a transdermal wire which carries $20-MHz$, AM-modulated carrier signals. When a header is detected in the data, a command is recognized and is loaded in the $15-bit$ data register. A command is composed of a $3-bit$ Opcode and a $12-bit$ Operand. There are 5 effective commands that can be executed by the mP. These include: LD to load parameters into an addressed channel, ST to start all the prepared channels simultaneously, GND to ground all the active channels while keeping all the channel parameters intact, TURN to revert the polarities of biphasic stimuli in active channels, and INIT to initialize the mP with all the channel parameters reset to zeros. The channel parameters in the $12-bit$ Operand specify the current waveform and channel configuration with three fields: $5-bit$

amplitude field, $3-bit$ address field and $4-bit$ channel status field. The latter includes status flags for individually or simultaneously driving channels, for grounding them or for changing their polarity (source to sink or vice versa).

Electromechanical specifications
A $1.5-\mu m$ CMOS process has been used for implementing the ASIC. Nevertheless, no information is given on power requirements or physical dimensions.

2.2.30 ASIC-based batteryless implantable telemetry microsystem for recording purposes (Parramon et al., 1997) [52]

Application scenario
In their paper, Parramon et al. devise an implantable telemetric microsystem for 2-channel, EMG recording, based on an ASIC which is mounted on a PCB with other discrete components. There is no battery included in this implant; power and bidirectional, digital data are communicated to the implant over an inductive RF link formed with an external unit. The long-term goal of the project is to acquire telemetered muscle signals in order to control an artificial prosthesis.

General overview
The overall system, termed Implantable Telemetry Unit for Biomedical Research (ITUBR) is based on the following parts: i) an internal unit for data recording and telemetry, and ii) an external unit formed by a transceiver part for communication with the implant and an attached, computer-based data-acquisition unit. A block diagram of the overall system is given in Fig.2.36.

Implanted part
The implant is based on a hybrid system where most of the required circuits are integrated in an ASIC but additional passive SMD elements such as capacitors, coils and diodes are off-chip. For this reason, a double-sided PCB has been designed implementing all recording and telemetry circuitry. Emphasis in this paper is put on detailing the telemetry component as the recording component is considered application-specific. In this latter component, two pairs of electrodes (for implanting into muscle tissue) provide differential signals to two channels which are, then, amplified and filtered. Time-multiplexing on the two signals is performed and the resulting voltage signal is converted to current (by a VI-converter) and subsequently fed to a current-mode, 8-bit ADC. The digital output is forwarded to the telemetry unit for transmission. Special control logic (conditioning control, CC) is also included in the recording circuitry for selecting none, one or both of the EMG channels for transmitting. This CC is manipulated by sending control data from outside the body to the implant.

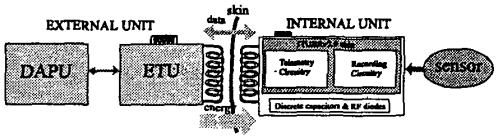

Figure 2.36: *ITUBR-system block diagram.*

The telemetry circuitry consists of a power-generation block, a receiver, a transmitter, a POR circuit and a second control unit. RF power is transmitted through an inductive link formed by two coupled coils (one external and the other implanted). The IC receives a fully rectified voltage and, through a line regulator, provides a $5-V$ supply voltage and several current references to the whole chip. Return-to-zero (RZ) coding has been selected for representing the command data issued to the implant and ASK for modulating the RF carrier which, at the same time, powers the implant. The receiver block simply implements an envelope detector for isolating the AC information signal on the carrier. This detector is composed of the input (over-the-air) signal passing through a diode, a bandpass-filter and a schmitt-trigger. The transmitter block, on the other hand, utilizes BPSK modulation due to its low sensitivity to noise, easy modulation and relatively easy demodulation in the external unit. The on-chip RF generator is obtained through a class-B driver in a resonant, parallel-LC, tuned circuit. The inductor is external but the capacitor is integrated. The transmitted RF-wave magnitude depends directly on the peak current through the coil, which can be programmed by 2 bits of an externally received command. The control unit is responsible for controlling the whole implant. It includes command decoding and data coding circuitry, a synchronization adapter and a $30-MHz$ clock generator. The decoder decodes the incoming envelope-detected, RZ-coded data. The synchronization adapter utilizes a serial-shift-parallel-load register for converting incoming clocked data trains (from the external telemetry unit) to data synchronized to to the on-chip oscillator. The clock generator is produced by a CMOS ring oscillator and clocks all ASIC circuits at a frequency of 30 MHz which is also the sync frequency for the synchronization adapter. Additionally, clock-divider circuitry is provided for clocking specific parts of the chip and outputs two sub-multiples 468 kHz and 234 kHz. Finally, the coder component of the control logic takes the digitized recorded data, codifies it and sends it back to the BPSK modulator with programmable, supported bit rates of 468 *kbps* and 234 *kbps*.

External part

The external unit of the system consists of the data-processing unit (DAPU) and the external telemetric unit (ETU). The DAPU is based on several programmable chips and a PC, interfacing between the user and the ETU. In this current version of the system, the connection between the DAPU and the ETU is not done by telemetry and is to be corrected in the future. The DAPU performs all data manipulation (coding, decoding, data storage etc.) while the ETU (placed close to the skin) only contains the minimum circuitry required to operate in order to reduce power consumption and size. This unit contains an RF power and data transmitter and a receiver. The transmitter is based on a class-E driver due to its high efficiency and its easy modulation in case of ASK modulation (as is the case here). The carrier frequency has been fixed at $l0\ MHz$ in order to achieve a high data rate, although lower frequencies are preferable for avoiding RF absorption by biological tissue, as well as to decrease the frequency crosstalk with the on-chip transmitter carrier. The ETU also contains a $30-MHz$ BPSK receiver to pick up the data coming from the implant.

Communication scheme
A specific communication protocol has been implemented between the implant control block and the external unit so as to achieve asynchronous, bidirectional data exchange. Data flow is mainly (but not exclusively) directed from the internal to the external unit. Initially, the implant is in stand-by mode until it receives a reset signal. It subsequently expects, receives, decodes and echoes back the next 8 incoming command bits. In case of corrupt transmission or error, a retransmission scheme is followed by the external unit. On successful command reception, the implant starts sending recorded EMG data out for an indefinite time period. For every 8 *bytes* of data it emits, it includes a synchronization byte. The central control block relays command information such as channel-selection, reset, clock and ADC-ready signals to the CC block. The latter, then, responds back with the digitized data.

Electromechanical specifications
The ASIC has been fabricated with a high-voltage, $2.5\mu m$, BiCMOS process and its area is approximately equal to 30 mm^2. Overall implant volume is 1 cm^3 and overall power consumption is 22.5 mW (4.5 mA @ 5 V).

Miscellaneous issues
Both in-vitro and in-vivo (in rabbits) tests have been performed. Some problems in the EMG recording circuitry have been encountered with the current version of the implant and a second, corrective version is under way.

2.2.31 Vaginal temperature sensing using UHF radio telemetry (McCreesh et al., 1996) [40, 39]

Application scenario

Women often use daily home recordings of their basal-body temperatures to indicate ovulation for both natural contraception and in-vitro fertilization purposes; a sub-lingual temperature rise of approximately 0.3^oC occurs at ovum release, with similar increases detectable at other body sites such as the axilla, rectum and vagina. Repetitive measurements with conventional probe thermometers are prone to placement, timing and manual-logging errors, even after careful instruction of the subject. To be useful, the measurement should be carried out at the same time every day and under identical physical conditions. Typically, a subject takes her temperature before rising each morning; variations in weekday/weekend waking habits, movement in preparation to take the measurement and readout errors all cause problems.

To enhance measurement accuracy and decrease user input, a telemetered temperature-sensing device for intravaginal application has been investigated. Programmable, continuous-time, temperature monitoring is achieved by a two-PCB and battery assembly, all housed in a tampon-like package which wirelessly transmits measurements to a bedside base station.

General overview

An overview of the system is depicted in Fig.2.37. A temperature-sensing circuit pulse-amplitude modulates (PAM) a UHF transmitter which emits readouts to the bedside station. This station consists of a receiver which recovers data and forwards it to a microcontroller-based platform for data logging. An attached LCD displays system status and measured temperature.

Implanted part

The implant is a two-part radio thermometer consisting of a low-power, temperature sensor and a transmitter block. The sensor is in virtue a thermistor (UUT51J1, Rhopoint) which is wired to a single low-power, CMOS op-amp (7611) configured as a relaxation oscillator. This oscillator effectively performs a conversion of measured data from temperature (voltage) to pulse-width voltage. The generated baseband pulse signal, with a duty cycle of no more than 3.1% for conserving battery power, amplitude-modulates a single-stage, surface-acoustic-wave-resonator (SAWR)-controlled transmitter bearing a carrier frequency of 418 MHz (UHF frequency band). For the

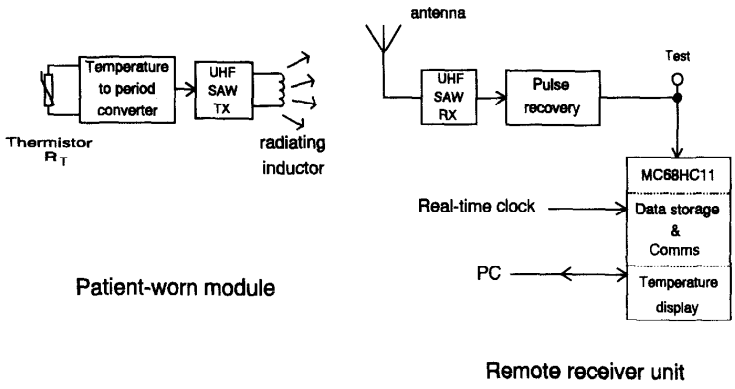

Figure 2.37: *Block diagram of the UHF temperature telemetry system.*

oscillator LC-tank, a simple inductor has been used as a small multi-turn antenna for minimizing volume requirements of the probe. Furthermore, it has been shown that data radiation through a lossy medium such as the human body, is much more efficient with this kind of antenna than alternative forms of radiating elements since tissue-absorption effects are reduced. Power for the probe-enabling circuitry is provided by a battery included in the same package.

External part

A super-regenerative receiver module (stabilized by a SAW delay line) recovers the temperature-bearing baseband pulses forwards it to a microcontroller-based circuit setup for data logging. The mC (68HCll, Motorola) used is a low-power chip with on-board memory and a timer system which can be triggered by edge-detector circuitry, a feature required to measure the pulse width of the recovered waveform. This measurement is, then, converted to a temperature reading and stored in on-chip memory. A microcontroller-driven LCD screen displays system status data and the last-received temperature. Special embedded software has been written in the mC for facilitating the data-logging functionality and can be configured to sample temperatures at set intervals throughout the day or night. This process relies on a real-time-clock module to interrupt the mP at intervals of one hour, minute or second. The prototype program takes a measurement every 5 min for a $1 - hour$ period during the night. A temperature resolution of 0.1^oC can be achieved with this system. This process is repeated for the required number of days in the female cycle. Data may be downloaded to a PC for trend indication at any time. When temperatures are not being recorded, the processor is placed in a low-power mode to conserve battery power.

Communication scheme

Communication between the probe and the bedside station is achieved by the former amplitude-modulating a $418 - MHz$ UHF carrier signal with pulse-width coded data. In practice, due to the RF signal passing through the vaginal walls, a lowering of the resonant frequency by about 6 MHz has been detected (compared to the "free-space" model). Thus, the LC-tank circuitry has been adjusted to transmit at 424 MHz. UHF operation has been specifically picked since it ensures a low level of man-made electrical noise which tends to corrupt data in lower-frequency radio links and, compared with earlier efforts in this area, there are no special receiving antenna requirements.

Electromechanical specifications

The whole telemeter has been built to fit into a tampon applicator which was epoxy-coated to give rigidity and dipped in hot paraffin wax before use; the complete assembly measured 18 mm in diameter, by 60 mm in length. A draw cord was used to facilitate device recovery. The RF section and the sensing oscillator occupy separate $10 - mm$ diameter PCBs which were mounted coaxially with a 6-V, 160-mAh LiMnO battery. With the UHF oscillator operating at 2.2 mA peak, the telemeter has a duration of about 100 days, enough to cover three female cycles.

Miscellaneous issues
The authors have actively been involved in limiting the effective radiated power of the device to 1 mW. In this way, they provided a system with an exposure well below the ANSI safety limit of 5 mW/cm^2. They also studied the effects of subject posture to the level of the transmitted telemetry signal for three cases: standing, seated and lying.

2.2.32 An implantable telemetry platform system for in vivo monitoring of physiological parameters (Valdastri et al., 2004) [69]

Application scenario

These days, more and more biomedical applications appear that strive to utilize biotelemetry to transmit physiological parameters from an implanted microsystem to the outside world. However, the authors of this paper identify the fact that existing designs do not actively take advantage of the microcontroller-based architectures and digital-codification techniques available for transmission in such systems. For this reason, they present a new, versatile implantable *platform* system that provides multichannel telemetry of measured biosignals. Its versatility resides in its ability to support different types of sensors and to allow for easy reprogramming so as to fulfill different application requirements. To demonstrate the correctness of the concept, a specific case study is implemented for gastric-pressure monitoring which is a PCB-mounted assembly, supporting up to 3 sensor channels. This implant can transmit digitally modulated data to an external receiver over a wireless link with robust error control.

General overview

The presented system consists of the microcontroller-based implant which can monitor and wirelessly transmit up to 3 channels to an external receiver. The receiver is also of custom design and connects to a PC for further data manipulation.

Implanted part

A simplified block diagram of the implant is given in Figure 2.38. The core component obviously is an $8-bit$ mC (rfPIC12F675F, Microchip Technologies, [65]) which includes - among others - an ADC and transmission module and operates at 4 MHz.

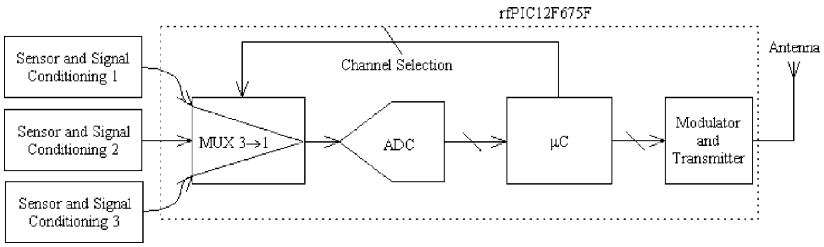

Figure 2.38: *Implanted-circuit block diagram.*

Up to 3 sensors can be attached to the implant and are fed to an on-chip multiplexer whose select signal is driven by the mC. Each analog channel features an input range of 3 V. The multiplexer output passes through an (on-chip) $10-bit$ ADC, which has a maximum sample rate of 25 $Ksamples/sec$ and produces 2 *bytes* for each sample. Its digital output is, then, sent to the transmitter which is a fully integrated ultra-high-frequency ASK transmitter consisting of crystal oscillator, PLL, power amplifier and mode control logic. A transmission frequency of 433.92 MHz has been selected from commercially available products in order to meet radiation strict requirements (to be discussed later). The carrier frequency is fixed and determined by an oscillating crystal mounted on the implant PCB, therefore, by selecting different carrier frequencies, more than one implant can coexist in the same area. The overall implant is powered internally, by a lithium battery.

The mC allows for low-power operation by typically supporting two modes of operation: active and sleep mode (where consumption is minimal). Swapping between the two modes as well as dynamically adjusting the sensor sampling frequency is totally relying on the specific firmware (i.e. embedded mC software) developed for the mC. For the specific application whereby gastric-pressure monitoring is required, firmware has been tailored to meet the physicians' needs as well as conserve battery power. The system specifications consist of acquiring one pressure sample every 30 *sec*, until it exceeds a fixed range centered in the value acquired at the beginning of the experiment, which is considered as the steady-state value. When the pressure exits from that range, 25 *samples/sec* have to be acquired for 30 *sec*; the final value of this acquisition becomes the new threshold value. This operation modality allows power saving during periods that do not possess relevant pressure information and a continuous monitoring when interesting events occur. This kind of "threshold monitoring" can be applied to almost all potential physiological parameters being monitored by adapting the two sample rates to the frequency band of the interesting signal. Software data filtering can also be performed by having the mC oversample the sensors at 50 *samples/sec* when the measured signal exceeds the steady-stage range. Then, an average value of these samples is send out making the readouts more noise-insensitive. Switching between the active and sleep mode is achieved by a (hardware) comparator which detects this "threshold" and sends a wake-up hardware interrupt to the mC for initiating sampling and then it goes back to sleep. It should be noted that the mC can be reprogrammed in-circuit, a fact that adds to its versatility. The telemetry system has been tested in vivo with a pressure silicon sensor (LL-3-072-15, Kulite Semiconductor). Conditioning of the measured signal is performed by amplifying it with a low-power, instrumentation amplifier (AD620, Analog Devices) which has been mounted on a separate double-sided, SMT PCB. The amplifier output is connected both to an input channel of the mC and to the threshold comparator.

External part
For the external part, a commercial, miniature receiver-and-antenna part (AC-RX, Aurel) has been used for ASK reception. This part has been mounted on a SMT-board and its output has been connected to a serial adapter (MAX233, Maxim). This second chip, converts inputted signal logic levels to RS232C-compliant data and allows direct connection to a standard PC COM (serial) port. A computer can then record and process the data as desired. For this purpose, a custom GUI has also been designed using Labview 7 Express software from National Instruments. This GUI allows for adapting to various applications, various data rates and number of read bytes etc..

Communication scheme
The implant transmits ASK-modulated digital data to the external system over the air. The data stream before transmission is encoded in the serial standard EIA232C with 2400 *b/sec*, 1 start bit, 1 parity bit, and 2 stop bits. Maximum supported data rate is 40 *kbits/sec*. In order to enhance transmission reliability, each data burst starts with 2 *bytes* containing the number "48", i.e. the ASCII encoding for "0" character. Moreover, for each transmitted bit, the mC evaluates the parity bit and includes it in

the serial codification.

Electromechanical specifications
Various packaging solutions have been investigated by the authors. Sought features were the easy and full recovery of the implant circuitry since the target was to develop a rapid-prototyping system for various applications which could be easily extracted, have its battery replaced and be re-implanted for further testing. With these considerations in mind, the device has been encapsulated in a two-part silicone elastomer (Sylgard 170, Dow Corning) using a cylindrical Delrin mold. Final dimensions of the package are 19 mm in diameter and 27 mm in height. The size of the implant PCB measures 18 mm $\times$ 9 mm $\times$ 5 mm (without the application-dependent conditioning circuitry). The power is supplied by a $3 - V$ lithium, coin battery (CR1025, Panasonic) with a capacity of 30 mAh at room temperature. Implanted-circuit operative lifetime is related to the algorithm implemented in the mC. For the specific case study, maximum battery lifetime is achieved if pressure never exits the initial range so that the sampling rate does not increase. For this case, the battery lasts approximately 2 weeks. On the other hand, the "worst case" could be represented by a pressure signal without steady state (i.e. continuous transmission of 25 samples/sec) which means a transmission of 50 samples/sec. If this event occurs, the operative lifetime decreases down to 56 h. This lifetime estimation does not consider power consumption of the sensor and its signal conditioning circuitry because this part of the system can change depending on the particular application.

Miscellaneous issues
The authors have actively investigated the carrier frequency to use for the telemetry link so as to minimize power transmission through human tissue. Thus, they have performed a sufficient degree of modeling of the body as a dielectric material and have plotted radiation conductivity (σ) and permittivity (ε) graphs over a large frequency range. The optimal frequency band has been found to be from 1 MHz to 1 GHz approximately, so a transmission frequency of 433.92 MHz has been selected based on commercially available products. Also, the maximum transmitter power (5.623 mW with a supply voltage of 3 V) has been checked for compliance with the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines. The measured quantity was 30 mW/m^2, much lower than the ICNIRP reference level of 2.17 W/m^2 (for a signal frequency of 433.92 MHz).

2.2.33 A microprocessor-based implantable telemetry system (Fernald et al., 1991) [21, 16, 22]

Application scenario

Commercial implants are usually forced to assume a modest degree of sophistication and adaptability in an attempt to respect tight requirements for low power consumption, small size and high reliability. The advance of low-power, high-density integrated systems, however, makes possible the design of more intelligent control units capable of supporting a much larger set of applications requirements. This observation has led Fernald et al. to conceive and design a novel, microprocessor-controlled, implantable telemetry system. This system is able to support (via a custom serial interface) a modular set of CMOS chips, each implementing different sensing and/or actuating functionalities. Bidirectional, transcutaneous communication between an external host and the implant (implemented as an extra CMOS chip) is featured through the exchange of incoming command- and outgoing data-payloads. Notably, the mP is (re)programmable in situ by the host through the telemetry module. Reliability, flexibility and modularity traits have actively been pursued in addition - typically - to low power consumption and small size. For proof-of-concept purposes, a specific sensor-interface chip for biopotential recording has been ported to the system. The work presented in subsection 2.2.21 (Smith et al.) is more focused on the issue of neuromuscular stimulation, yet bares some resemblance to the current design since both attempt a generic approach (i.e. an implantable-system platform) to the specific biomedical field.

General overview

The proposed system is built to typically support an implant communicating wirelessly with an external host for command and data exchange. Nonetheless, emphasis in this paper is placed on the system architecture of the implant and the featured functionalities that make it flexible. An abstract overview of the system is given in Fig.2.39.

Implanted part

The proposed system architecture, illustrated in Figure 2.39, consists of a modular chipset interconnected by (unidirectional) *serial command* and *response buses* plus control signal lines (clock, reset, interrupt-request). A custom mP serves as the bus controller and provides the flexibility necessary to satisfy a variety of application requirements. In addition to system configuration, functions such as information processing and closed-loop actuator control can be implemented via software. Serial (as opposed to parallel) busses offer several advantages related to system requirements. Such advantages are: i) the lower number of wires required to connect the ICs, and ii) the elimination of address-decoding

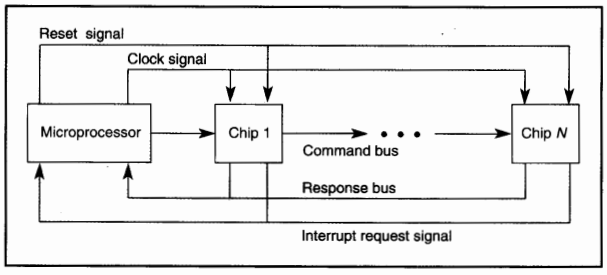

Figure 2.39: *Block diagram of system architecture.*

components (implicitly implemented in the bus protocol), both of which improve system reliability and volume. The latter feature also allows for easy system expansibility; since all address decoding is accomplished by bus protocol, any number of peripherals can be added to the system without redesigning existing components. The disadvantage of using serial basses is the reduced throughput which, nonetheless, does not significantly impact system performance due to the low bandwidths (less than 1 kHz) typical of biological signals. This effect is even less critical due to techniques used to hide the serial-bus inherent latencies.

The mP transmits command frames to the system peripherals (Chip 1, Chip 2, ..., Chip N) through the command bus. All command frames consist of a combination of six possible fields (start bit, 3-bit command, 16-bit address, abort bit, 16-bit data, stop bit) and are shifted onto the command bus from left to right (LSB-first). As a command frame is shifted onto the bus, it is examined by each peripheral and then passed on to the next in a daisy-chain fashion. The Interrupt_Request signal can be strobed by any of the peripherals (in a wired-OR fashion). After interrupt strobing, a peripheral waits for a valid Acknowledge_Interrupt command, after which it returns an interrupt vector on the response bus. The microprocessor uses this 16-bit vector as the starting address of the appropriate interrupt service routine, thereby avoiding the overhead associated with a local vector table. All peripherals put information on the response bus, in reaction to Read (data) or Acknowledge_Interrupt commands by the mP. Response frames consist only of three fields (start bit, 16-bit data, stop bit) and are shifted onto the response bus in the same manner as commands. The address decoding of the bus protocol ensures that no two peripherals drive the response bus simultaneously. This address decoding involves each (serialized) peripheral manipulating the abort bit and address bits of a new command frame in such a way that, the peripheral to be accessed, forces subsequent peripherals to ignore the command frame. This scheme allows passing a frame between devices with only 1 *bit* delay. The daisy-chain also establishes interrupt priority by allowing the first peripheral that sees an Acknowledge_Interrupt command to accept, thus forcing other devices requesting an interrupt to wait for the next acknowledgment. It should be noted that the telemetry unit is implemented as one of the peripheral chips of the system, thus, interfacing to the mP through the serial busses.

For the mP (termed PERC) itself, a 16-bit, general-purpose, custom design has been employed which has been based on the Hector mP with several features added to support system requirements. Such features are Instruction-Set-Architecture (ISA) commands that support vector operations for signal-processing purposes common in biomedical applications (e.g. band limiting, data compression, event detection, FIR). Additional mP requirements include resetting peripherals, servicing interrupts and controlling serial bus transactions and the system clock (10 MHz). To allow fast prototyping of a flexible research instrument, programming is performed through telemetry, either before or after the implantation. In total, the processor has 39 instructions, 14 general-purpose (16-bit) registers (plus the program counter and stack pointer), an 8-bit flag register, 16 *kbits* of instruction/data SRAM and two on-chip, programmable timers ($0 - 65$ $msec$ range for a mP clock of 10 MHz). Through these instructions the mP can go into

sleep mode for cutting down in power consumption and can wake up when triggered by external activity (through the telemetry unit). The fact that data can be stored in the SRAM as well as the support of read/write buffering to the serial bus are both both functionalities that hide the inherent bus latencies by reducing bus accesses, in the former case, and by overlapping bus I/O time with instruction execution, in the latter. It is notable that in order to expand system memory, an SRAM peripheral can also be used.

The mP maintains complete control of the telemetry unit through the serial bus. The telemetry unit has several registers that allow the processor to control and monitor the units operation. The most important of those are the command register and the control/status register pair. The processor may instigate a transmission by writing data into a FIFO stack and then writing a proper value to the command register. Receive_Complete and Transmit_Complete interrupts are included for informing the mP when the telemetry unit is free for new operations. A full-featured protocol is developed for the over-the-air transmission of data with checksum and timeout checks performed on each new packet. Therefore, one more interrupt, Error, alerts the mP of abnormal data transmissions and a last one, Timer, is associated with a programmable timer for putting the mP out of sleep mode after a preset interval. Since the mP is booted through the telemetry unit, the FIFO must be large enough to contain a reasonable bootstrap routine and, thus, a $64 - word$ size has been selected. Data transmission and reception is performed through a single-coil antenna on an RF carrier of 40 MHz for complying to FCC regulations. Transmission uses PSK on a continuous RF carrier with an average data rate of 100 $kbits/sec$ (the actual rate varies with data content). To achieve high power efficiency, the transmitter must operate at the resonant frequency of the tuned antenna, therefore a VCO has been included which searches for this frequency at the start of each transmission. For reception, a simpler PWM scheme is adequate since the power delivery to the receiving coil by an external transmitter is not an issue.

The sensor-interface peripheral designed for this architecture for proof of concept, is a programmable signal-conditioning and acquisition chip intended for biopotential studies. The chip provides 8 differential analog input channels which are compatible with a variety of sensors (e.g. strain-gauge bridges, resistive transducers). Each channel contains a programmable-gain stage that provides full-scale input ranges from ± 5 to ± 100 mV. The amplified signal is then band-limited to a programmable frequency between 150 Hz and 10 kHz, after which it is multiplexed into a 10-bit ADC. The resulting digital samples are stored in small FIFOs until they are read by the mP through the serial bus.

External part
As discussed above, no information is given regarding an external setup.

Communication scheme
A full telemetry protocol has been implemented as part of this system specification. Each transmission block to or from the telemetry unit contains five possible components: a header, a 16-bit command field, a 64-word data field and two 16-bit command/ and data checksums for error detection. The (implant) transmission header is a period of

unmodulated carrier approximately 80 μsec in length, allowing the external receiver time to detect the carrier prior to the start of data flow. The reception header consists of a series of zeros, approximately $3 - msec$ long, followed by a single (start) bit. This unusually long receive header alerts the telemetry unit to the upcoming transmission. To conserve power, the receiver circuitry is activated only once every 3 $msec$. If no carrier is detected, the receiver is turned off immediately; otherwise it remains active until the telemetry transaction is complete. Since the receiver is off most of the time, a header length of at least 3 $msec$ is required to ensure recognition of the transmission. The command field allows the implant system to exchange 14-bit command or status information with an external control station. This field is actually 16 $bits$ long, but 2 $bits$ are predefined by the telemetry protocol. The MSB indicates whether that transmission contains a data field and data checksum. This allows transmission of either a single command or a command followed by a 64-word data/program block. The second MSB indicates whether the data field represents a bootstrap routine for the mP. If this bit is set, the telemetry unit asserts a mP reset operation and waits for the bootstrap routine to be requested. Words are transmitted LSB first. To allow the protocol to accommodate a large number of handshaking schemes, single-word commands may be transmitted and received without destroying the FIFOs contents.

Electromechanical specifications
This paper discusses the principal functions and structure of the implantable system. It, therefore, discusses no physical dimensions of an actual chipset implementation or package, which are also dependent heavily on the per-case attached peripheral modules. Also, no power consumption estimates are given, even for the mP core. Yet, even though not specified, a battery is assumed for powering the implant.

Miscellaneous issues
The authors actively discuss the issue of clock-frequency and clock-distribution-network selection. The task of selecting a minimal but meaningful clock frequency is not trivial and is imperative for keeping power consumption in CMOS circuits as low as possible. With software programs implementing typical biomedical measurements and with highest sampling frequencies in mind, a lower limit to the clock frequency has been fixed at 10 MHz. As far as clock distribution is concerned, a distributed (as opposed to centralized) policy has been picked, in which a continuous clock is fed to the bus and all peripherals but each peripheral module is responsible for generating any additional clock for its own function. In this way, high current drain is averted at the cost of increased inter-chip clock-skew phenomena which are solved by utilizing a differential signal (here: a sinusoid).

2.2.34 The development of a microprocessor controlled implantable device (Harrigal et al., 1990) [31]

Application scenario
Harrigal et al. describe a flexible, implantable pacemaker (Kelvin II, Cook Pacemaker Corp.) which is based on a custom mP design. This is a rate-responsive, dual-chamber (atrial-ventricular) pacemaker which is implemented on two CMOS IC chips (termed Pacer and Micro). There is a double benefit in this implementation: While dual-chamber pacing offers atrial-ventricular synchrony to an atrial rhythm, sensing of blood temperature offers rate responsiveness in a patient with atrial rhythm that is intermittent, inappropriate for tracking or chronotropically incompetent. Apart from heart pacing, the proposed device can also act as a truly diagnostic implantable device by allowing cardiac-signal measurement, storage and transmission to a physician's workstation for evaluation.

General overview
Emphasis in this paper is placed on describing the main two chips and the simulation/verification process followed. As such, no information is given on the telemetry implemented on the pacemaker for communicating data externally nor for any external host assembly, for that matter.

Implanted part
The implant consists of two custom chips, one Micro-chip containing the digital mP and one Pacer-chip containing the analog circuitry interfacing to the driven stimulation leads an the telemetry unit. Both chips are mounted on a hybrid circuit which also contains external components such as larger capacitors, resistors or antenna coils. The Pacer-chip contains the pulse-generator output circuitry, sense amplifiers (for detecting QRS complexes), a rate limiter, a programmable ADC for converting measured cardiac signals to digital form, programming and telemetry circuitry, watchdog (continuous, high-reliability testing and backup circuit) and clock circuitry. The Micro-chip, on the other hand, contains a complete 8-bit mP, 4 *kbytes* of instruction ROM, 2 *kbytes* of data RAM and one external port. The mP contains 3 registers for data manipulation and an enhanced (compared to prior implementations) instruction set which enables reduced program-code size and more sophisticated functions in the pacemaker. Two interrupt lines are included, one maskable, the other not. The non-maskable interrupt is triggered whenever a QRS complex is sensed or the pacemaker paces. These events have the highest priority and, thus, must be serviced by the mP immediately. Needless to say, the corresponding interrupt service routines can not be preempted by other tasks of the mP as their execution is time-critical. In contrast, the maskable interrupt bears lower priority and can be triggered by the programming and telemetry circuitry or by the Alert timer. This Alert state virtually is a power-down state wherein the mP enters to conserve battery power when no interrupts need to be serviced or no program is being executed in the pacemaker. This state allows to reduce the average current in the Micro-chip to less than 3 μA and is exited on new interrupt or reset signal.

The ROM is the program memory of the pacemaker and contains all pacing and sensing programs running in the implant, which change depending on the mode settings. Also, the ROM contains the programming and telemetry routines, the algorithms for the blood temperature rate adjustments and the program which controls the ADC functions. In the ROM, new modes, algorithms and programs can be inputted increasing the flexibility of the pacemaker device. Inside the RAM, the mP can store and retrieve run-time settings and variables that control the pacing parameters as well as diagnostic parameters such as the rate histograms. The 2 *kbytes* of RAM cover almost half of the total area of the Microchip, yet its inclusion bears advantages. Apart from pacing, the implant can also work as a diagnostic microdevice by recording several events and storing them in the RAM. These events include 1 to 10 *sec* of digitized internal-ECG data, long/short-term histograms, blood temperature and algorithm parameters. Also, segments of program code can be included in RAM and executed as subroutines to the main program (in ROM), effectively extending the pacemaker functionality. The RAM incorporates shutdown and precharge control circuitry for minimizing power consumption.

External part
No details are given on any external host system responsible for communicating with the implant.

Communication scheme
No details are given for the communication scheme implemented apart from the fact that telemetry (i.e. wireless connectivity) is utilized.

Electromechanical specifications
The IC chips presented above, have been fabricated with 2 μm CMOS technology. The overall pacemaker consists of the two chips, a hybrid circuit onto which they are mounted, a battery and a hermetically-sealed case. Physical dimensions and power consumption are not discussed.

2.2.35 An implantable telemetry device to measure intra-articular tibial forces (D'Lima et al., 2005) [17, 66, 68, 67]

Application scenario

The development of improved implantable devices and materials requires knowledge of their in-vivo behavior. However, little is known about the actual loads borne by orthopedic and other implanted devices in vivo. Direct load measurement would provide extremely valuable information, for the improvement of device designs and for the rapid rehabilitation of individuals in which devices have been implanted. For providing this kind of information, D'Lima et al. are proposing a new multichannel, telemetry, implantable, hybrid-CMOS system combined with strain gauges. The implant is powered through an inductive couple over which it also transmits data from piezoresistive elements. Compared to existing implementations, this new implant bears programmability features which allow a multitude of different sensory elements to be interfaced to it.

General overview

The presented device is targeted for placement inside (total) knee implants. Externally, a hand-held receiver is built which acquires the data from the implant and forwards them to a computer for storage and display purposes. For providing power to the implant, another coil is driven and magnetically coupled to the receiver coil of the implant.

Implanted part

The developed telemetry implant (termed StrainLink) is developed entirely from off-the-shelf SMD ICs. A block diagram is provided in Fig.2.40. It consists of a signal-conditioning IC, a mC and an RF oscillator chip with external antenna. The signal-conditioning chip used (AD7714, Analog Devices) includes a bridge for signal conditioning, an analog multiplexer, an ADC and programmable gain and filter functions. The AD7714 features 3 true differential bridge inputs (i.e. channels) and software programmable gain of 1 to 128. The LP-filter is software-selectable in a range from 1 Hz to 250 Hz for each channel. The ADC features 22 bits of resolution with the filter cut-off frequency at 1 Hz and 10 bits with the cut-off frequency at 250 Hz. The supported sample rate is 220 Hz divided by the number of active channels. The 8-bit mC (PIC16C, MicroChip Technologies) primarily exists for allowing the AD7714 to be reprogrammed through the serial port of a PC. Once programmed, the configuration is stored in nonvolatile, electrically erasable, programmable, read-only, 72-byte memory (EEPROM) on the mC. On power up, the mC reads the EEPROM to configure the AD7714 for the appropriate channel-specific gain, filtering and sample-rate parameters. The mC also performs pulse-code modulation (PCM) of a surface acoustic wave (SAW) RF oscillator (RF Mono-

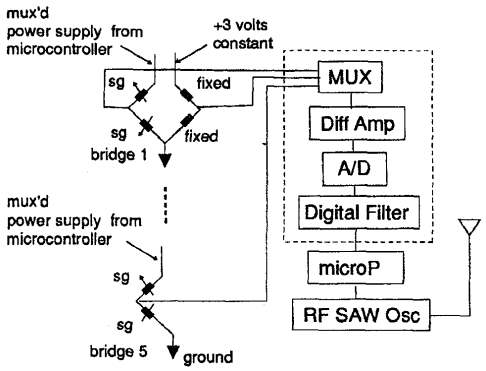

Figure 2.40: *Telemetry block diagram.*

lithics) with the data to be broadcast externally at a rate of $4800 bits/sec$. Finally, the implant also consists of voltage-rectifying and filtering circuitry that receives induced power from an external transmitter for providing supply voltage to the AD7714, mC and RF oscillator.

External part
The external PCM receiver contains a matched RF SAW oscillator and a level converter to generate RS-232 signals from the PCM data stream. These data are, then, forwarded to a PC which is running custom software for reading, displaying and storing the received data. The whole receiver module along with a battery for providing power, is included in a hand-held enclosure. Apart from the receiver part, a second (transmitter) coil provides induced EM-power to the implant. A function generator is used to provide a $3 - V_{p-p}$ signal at 1.6 kHz to a $100 - W$ audio power amplifier (Samson, Inc.) for driving the transmitter coil.

Communication scheme
PCM modulation over a $916 - MHz$ RF carrier has been used for data transfer from the implant to the outside world. According to the authors, it is advantageous because it is relatively less prone to interference compared to pulse width modulation (PWM) and pulse interval modulation (PIM). Furthermore, with PCM errors in RF transmission can be detected. This is accomplished by sending a checksum byte, which is the sum of the preceding data bytes. At the receiver, if the sum of the data bytes does not equal the checksum byte, then an error flag is generated at the PC-based receiver.

Electromechanical specifications
The dimensions of the implant circuitry are 14.6 $mm \times 30.5\ mm \times 6.5\ mm$ and the power consumption is typically 9 mW (2.8 mA @ 3 V), including the RF link. The telemetry device has displayed a low bit-error rate (BER) of 0.5 ppm and a low thermal drift of $0.003\%/^oC$ (over the range $15^oC - 50^oC$).

Miscellaneous issues
The telemetry system has been tested with a wide variety of different sensors (both DC and low-power, AC ones) to verify compatibility. Also, the RF carrier frequency for radiating power to a device inside a titanium knee implant has been carefully selected (1.6 kHz) to minimize losses to shielding and eddy currents.

2.2.36 Design of miniaturized telemetry module for bi-directional wireless endoscopy (Park H.J. et al., 2003) [49, 50, 37]

Application scenario
Endoscopy is currently performed by advancing fiber-optic wires inside the human body. Drawbacks of this technique - among others - are patient discomfort and limitations on how far endoscope tips can advance into the small bowel. To eliminate such problems, miniaturized, swallowable, telemetry capsules have been developed which bear image sensors for capturing and transmitting externally in-body pictures as they descent from the esophagus to the thick bowel. Original work on such capsules has been performed with the M2A capsule [41].

Nonetheless, important issues, namely in-body camera control, effective illumination and multichannel measurement, still need to be resolved in current implementations. In this context, the authors have developed a new telemetry, miniaturized capsule for wireless endoscopy. This new device features an image sensor and bidirectional communication consisting of transmitting image data and (simultaneously) receiving commands for controlling the capsule electronics.

General overview
The overall system is depicted in Fig.2.41. The capsule captures, AM-modulates and transmits an NTSC-type, analog, color video signal which be directly received (by a TV-tuner) and displayed with e.g. a TV. The AM signal is received by antennas taped to the patient body. Further, an external controller module transmits commands over a separate RF link to the capsule for controlling its functionality.

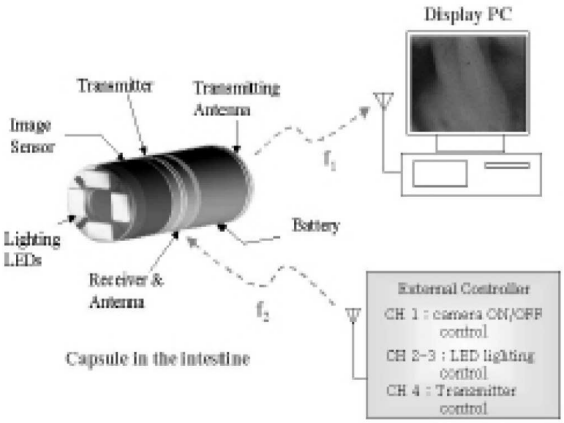

Figure 2.41: *Conceptional diagram of bi-directional wireless endoscopy system.*

Implanted part
Two consequent implementations of the overall system have been described. In the first one, the functionality of the capsule is principally very simple. The primary component is a CMOS image sensor and lens for acquiring in-vivo pictures of the intestine. It is a single-chip 1/3-inch format video camera (OV7910) which outputs NTSC-type video signal. It has a very low power consumption and requires a $5-V$ DC supply. Four LEDs are also mounted on top of the sensor for illuminating the tissue area to be captured. Next, a transmitter circuit is used for sending the video signals to the outside world. It includes a local oscillator which generates an RF carrier signal in the UHF band of 315 MHz which is the commercial cable channel frequency for cable-TV broadcasting systems. The NTSC video signal from the sensor is AM-modulated on this carrier, amplified and broadcast by a small loop antenna inside the capsule. By transmitting in this UHF band, users can watch the

images of the intestine on a TV directly, using channel 39 (hyperband cable channel). A second small loop antenna is included in the capsule for receiving OOK-encoded commands from an external controller. This antenna feeds the data to an RF receiver circuit which is a commercialized OOK superheterodyne SMD chip. The IC includes an oscillator tuned in the reception frequency of 433 MHz and the demodulated, serial commands are fed into a decoder chip. Through these commands, an external user can switch the capsule camera and/or any number of the four illuminating LEDs on or off. In effect, power consumption can be limited and proper illumination of the capture intestine can be achieved. Power to the capsule is provided by an included battery pack. All circuits and components in the capsule are driven by a single, high-output-current amplifier. All described components are mounted on one PCB.

In the second version of the described system, all image encoding, command decoding and controlling functions in the capsule are performed by a single CPLD (complex-programmable-logic device) controller chip. The control that the CPLD (XCR3064-cp56, Xilinx) implements includes *individual* powering of the image sensor, the illuminating LEDs and the data transmitter circuit. Clock and reset signals are also generated by the CPLD. A significant difference with the previous implementation is that in this case the sensor output is not an analog NTSC signal and is not transmitted as a UHF signal externally. In contrast, 8-bit image data and vertical, horizontal and pixel sync are the information provided by the sensor and are encoded by the CPLD before transmission over the UHF band. Since the sensor output is not always valid, the CPLD also picks up the task of correctly timing its sampling periods. Finally, in this version, FSK modulation has been applied on the sensor data at 1.2 GHz and the supported data rate has been equal to 2 $Mbits/sec$ (at a CPLD frequency of 4 MHz). The control signal has remained the same, i.e. OOK modulation at 433 MHz.

External part
The external controller is user-operated and is responsible for manipulating the functionality of the capsule by transmitting commands over a wireless link (different from the one used for reception). Similarly to the capsule implementation, two versions of the controller have also been developed. In the first one, four mechanical switches (channels) which select the on/off operation of the capsule components, are encoded to a digital command signal. This signal is, then, fed into a frequency-synthesizer and modulator (HM8134-2, HAMEG) and is modulated into an RF signal using an OOK transmitter with a carrier frequency of 433 MHz. Finally, it is amplified and transmitted through an antenna to the capsule. This version of the external controller is a table-based unit with dimensions 20 cm $\times$ 30 cm $\times$ 15 cm.

In the second version, two external controllers are built; one command encoder and transmitter and one video image decoder since - in this case - the data from the capsule are digital in form rather than a simple UHF, analog signal. A second CPLD (EPM7064-pc44, Altera) has been used for implementing the external encoder and an FPGA (EPF10k100ARC, Altera) for the external decoder. The external encoder is - functionally speaking - identical to the one of the first version with the CPLD imple-

menting all above described functions. The task of the external decoder is to combine the digital data from the sensor by properly manipulating the 8-bit image data and the three sync signals. No further circuit details are provided for either external module.

Communication scheme
Communication in the first system version is rather straightforward with the analog signal being directly AM-modulated in the capsule and demodulated in an external TV-tuner and display device. In the second version, image-data sampling is timed based on the internal (capsule) clock along with signals representing the horizontal, vertical and pixel syncs. All these digital-pulse trains are encoded by the CPLD into a single output signal which is the piggy-backed on an FSK-modulated RF carrier. In the external-decoder side, the process is reversed and image frames are reconstructed from the pixel and sync information. The image is resynthesized by an interpolation method.

The commands are composed of a 5-bit address and 4 consequent data bits. Though not explicitly stated, the address is assumed to serve the purpose of selecting a specific capsule. The 4 data bits are included for controlling the powering of the image sensor and the illuminating LEDs. The capsule can simultaneously transmit image data and receive commands.

Electromechanical specifications
The first version of the capsule has a diameter of 11 mm and a length of 7 mm and the second 12 mm and 30 mm, respectively. Power consumption for the second version is 66 mW (20 mA @ 3.3 V) when all components are turned on and 29.7 mW (9 mA @ 3.3 V) when only the CPLD and receiver are turned on. For the first version, no power figures are given.

Miscellaneous issues
In-vivo tests have been performed in animal subjects (dog and pig) with very good results.

2.2.37 An implanted device for stimulating paralyzed vocal chords (Harrigal et al., 1992) [32]

Application scenario

This paper is involved with the restoration of speech in patients with unilateral paralysis of vocal cords (i.e. paralysis in only one of the two cords). An implantable device has been developed which allows synchronous phonation of both the paralyzed and intact cord. It achieves this by stimulating the paralyzed cord on trigger either from signals coming from the cricothyroid muscle or from an external-unit telemetered signal which forces stimulation. Difference in sense signals from the cricothyroid muscle between *phonation* (i.e. speech) and *respiration* (i.e. breathing) were used to set the threshold level which triggers the paralyzed side. Additionally, the implant is also capable of telemetering such sense signals to the external unit.

General overview

The conceptual drawing of the overall system is given in Fig.2.42. It consists of the implant bearing a sensing and a pacing (i.e. stimulating) electrode and an external control unit for receiving telemetry data from the implant and also for forcing stimulation by the implant to the paralyzed cord, both over RF links.

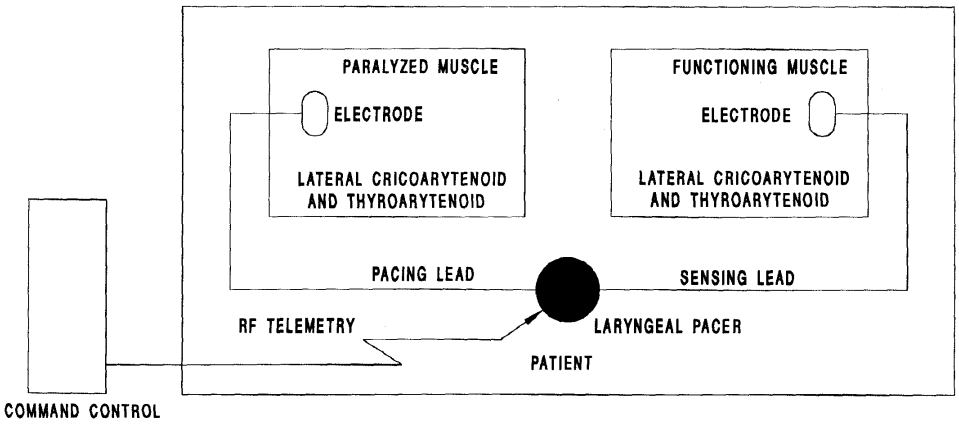

Figure 2.42: *Overview of vocal-cord stimulating system.*

Implanted part

The implant is a custom device similar in size and shape to a cardiac pacemaker. Two electrodes are used, one for sensing and one for stimulating, and are connected in bipolar configuration. On external control-unit command, the implant can deliver stimuli to the paralyzed cord. The device supports various configurations for these stimuli. The adjustable parameters are: the stimulation period, the voltage level from 1 to 7 V, the pulse width from 0.05 $msec$ to 1.5 $msec$, the repetition frequency from 1 to 200 Hz and the number of pulses from 1 to 1000. The implant is also capable of telemetering sense-level signals generated by the functioning muscle and measured by the sensing electrode of the implant. By experimenting with the above parameters and by studying these sense levels, the authors have been able to determine the threshold levels necessary for stimulating the paralyzed muscle. As previously mentioned, stimulation can be achieved on demand (by activating the external unit) or in synchronous mode, by activation from the functional muscle (during phonation).

External part
With the toggling of a switch, the control unit can transmit a command to the implant to deliver stimuli with various parameters, as discussed above. Also, by wirelessly receiving sense levels, as measured by the implant from the functioning muscle during phonation and respiration, the control unit is able to adjust the parameters of the transmitted commands so that the implant delivers appropriate stimuli. With this kind of closed-loop system, phonation levels have been defined (at 0.8 mV, here) as well as simple respiration levels (at 0.3 mV, here). Once a threshold level has been determined by studying the telemetered data, the value is stored in the implanted system.

Communication scheme
The implant and the external command control unit communicate over inductive RF link(s), yet no further information is given on the communication scheme implemented, on the form of the implant transmitted data or the structure of the control-unit issued commands.

Electromechanical specifications
No information is given regarding the implant physical dimensions or its power requirements. It is only known that it bears a size similar to a common pacemaker and there is no discussion on the powering scheme used (i.e. included battery, induced power etc.).

Miscellaneous issues
For in-vivo testing of the system, three dogs have been used in which the cricothyroid nerve has been severed to interrupt stimulation to their vocal cords. The sensing levels generated by the functioning muscle were consistent in the implant and on the external unit over a test period of three months and between all subjects.

2.2.38 A wireless single-chip telemetry-powered neural stimulation system (Von Arx et al., 1999) [3]

Application scenario

The authors identify the need for medical implantable microelectronics with very low power consumption and small size. For this reason and in the presence of other contemporary implementations consisting partly or totally of discrete components, they are proposing a new fully integrated, monolithic, implantable device for multichannel, neural stimulation. This system is designed for attachment to a nerve of the PNS through a cuff electrode and deliver adjustable, biphasic stimuli while receiving commands and power from an external RF inductive link. Apart from limiting the power and size factors, such an approach can additionally relax assembly and testing costs.

General overview

The implant is designed so that it receives power, data and a clock signal from some external host over an inductive, unidirectional link. A system overview is given in Fig.2.43. No further information is given for such a host system.

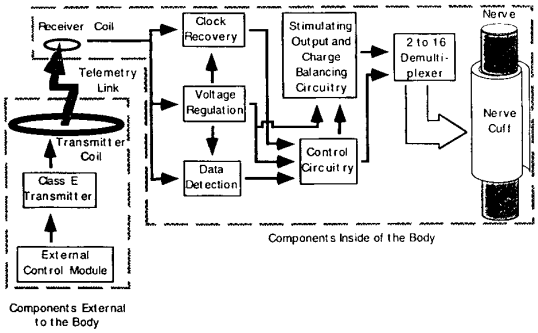

Figure 2.43: *Block diagram of the FINESS chip and external control.*

Implanted part

The implant is called fully-integrated neuromuscular electrical stimulation system (FINESS) and typically consists of an analog front-end circuit for properly capturing and handling the transmitted RF waves, a digital circuit for controlling the overall implant and an analog output circuit for delivering analog stimulus pulses to nerves. The analog front-end includes a tuned RF receiver with on-chip coil. The circuitry includes a $4 - V$ regulated DC supply generated from the full-wave-rectified, received RF signal. The front-end circuitry also includes a 500-kHz clock generator, chosen to reduce power while maintaining $2\ \mu - sec$ resolution for the systems stimulating output. The clock is generated by rectifying the received $4 - MHz$ RF signal and dividing it down. Generating the clock in this way ensures that it does not drift with respect to the external transmitter and control circuitry. The analog front end also includes data demodulation circuitry, which extracts the envelope of the received RF signal by bandpass filtering. Finally, it consists of POR circuitry.

The digital portion of the FINESS chip is strictly CMOS and has 4 functions. First, it recovers the pulse-width encoded data from the demodulated envelope. Second, it stores the recovered data. Third, it checks the received data for proper start codes, device address and parity. Finally, it controls all timing, amplitudes and switching of the output to the electrodes. For these functions, 5 major blocks are built: a single $10 - bit$ counter, logic to decode the counter value, a $45 - bit$ data register, logic to check parity and device address, and a 16-state FSM for overall control.

The analog output portion of FINESS consists of a $5-bit$ DAC output current source which can deliver current amplitudes up to 2 mA and low-resistance output switches. The output current is directed selectively to one of 8 possible pairs of attached electrodes by the output switches. The interphase delay in the delivered biphasic currents is programmable; each phase has a (5-bit) programmable amplitude of up to 2 mA and a 10-bit programmable duration of up to 2 $msec$. The system is capable of stimulation frequencies of over 150 kHz.

External part
Information about a potential external controlling system are limited to a control module which drives class-E transmitter and antenna for transmitting power and encoded data over an inductive link.

Communication scheme
Communication in the system is unidirectional, i.e. from the external to the internal module. Data is transmitted to the FINESS chip at 8.3 $kbits/sec$ by pulse-width encoded, amplitude modulation of the $4-MHz$ carrier. 40 data bits, 5 error detection bits and 2 unique synchronization pulses are transmitted for each stimulation event. Strict error detection is used and any detected error causes the system to abort stimulation.

Electromechanical specifications
The system mixed-mode, BiCMOS circuitry contains $3,100$ transistors and is 2.0 $mm \times 8.7\ mm$ in area. BiCMOS offers high-voltage protection (the on-chip receiver coil generates up to 30V) and allows full-wave rectification of the received RF signal. The fabrication process is $3\mu m$, double poly, p-well CMOS. This chip consumes 14.8 mW (@ 4 V) during full-scale $2-mA$ stimulation and 6.28 mW (@ 4 V) when not stimulating. Power savings are obtained over previous implantable stimulation systems by reducing system clock speed, reducing bias currents and by running the entire circuit from a single $4-V$ supply.

2.2.39 Analog wavelet transform employing dynamic translinear circuits for cardiac signal characterization (Haddad et al., 2003) [27, 28]

Application scenario

In subsections 2.2.11 and 2.2.13, neural-network circuits have been proposed for classification of two arrhythmia types: Sinus Tachycardia (harmless) and Ventricular Tachycardia (VT) with 1:1 retrograde conduction (potentially fatal). Front-end circuits have been developed for inclusion in ICD systems. In order to distinguish between the two types, these circuits perform morphology study of the cardiac QRS complex and trigger the ICD when pacing or shock therapy is in order.

In the current paper, the authors have introduced a new approach to the (more generic) characterization of cardiac signals. They have developed an analog QRS-complex detection circuit based on the Wavelet Transform (WT). WT is a very efficient tool for local analysis of non-stationary and fast transient signals. By proposing an analog - in nature - WT filter, they have avoided the use of DSP, and, thus, of the required ADC for implementing it, which is rather power expensive for a pacemaker. Again, a front-end IC is aimed at for attaching implantable pacemaker devices with ultra low power requirements.

General overview

As mentioned above, the discussed system is a front-end add-on for implantable pacemakers or ICDs, thus external-host and communication-scheme information is not applicable in this case.

Implanted part

The structure of the classifier chip is given in Fig.2.44. It consists of two major stages: the filtering and the decision stage. The former in virtue is a WT filter while the latter is further broken down into an absolute value circuit, a peak detector and a comparator. The main idea of the WT is to look at a signal at various windows and analyze it with various resolutions. It depends upon two parameters, being scale α and position τ. For smaller values of α, the wavelet is contracted in the time domain and gives information about the finer details of the signal, whereas for larger values of the scale factor, a more "global" view of the signal is obtained. In the specific circuit instance, 5 non-overlapping α scales have been implemented in parallel so as to compute the WT in real time (for the whole range of a cardiac signal).

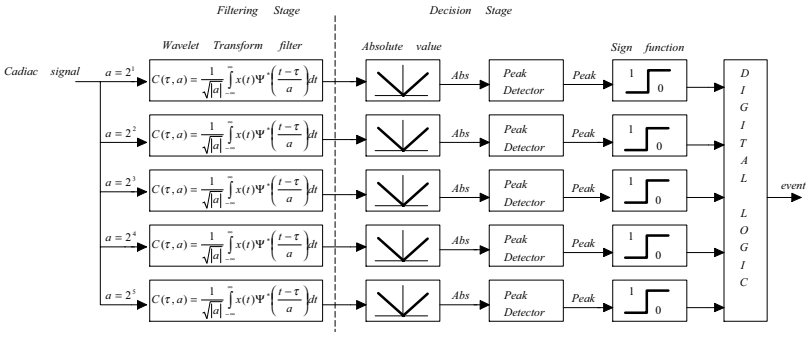

Figure 2.44: *Block diagram of the wavelet system.*

The design of the analog WT filters has been based on a technique known as Dynamic TransLinear (DTL) circuits which allows the implementation of linear or non-linear, polynomial, differential equations. Each WT filter is, in fact, an analog band-pass filter of which the impulse response is an approximated first-derivative gaussian-window function. For the approximation, a 3-stage cascade of Complex First-Order Systems (CFOS) has been used (and implemented in DTL circuits). Generally speaking, the larger the number of stages, the better the approximation to a gaussian function is obtained but at the cost of larger noise distribution or, equivalently, larger current consumption to overcome the effects of noise accumulation. In order to implement a Wavelet Transform, we need to be able to scale (α) and shift (τ) this gaussian function in time. This is achieved by changing the values of proper in-circuit capacitances accordingly, and, thus, short windows at high frequencies and long windows at low frequencies can be created.

Next, the output signal of each WT filter is passed to the decision stage where it is fed to an absolute-value circuit followed by a peak-detector circuit. The combination of these two blocks effectively creates an adjustable threshold level. Finally, the last block is a comparator for detecting the modulus maxima positions (Q and R) of the QRS complex. The generated temporal information of the modulus maxima are, then, passed to a digital logic circuit which uses them to classify the characteristic points of the cardiac signal, as seen in the right side of Fig.2.44. However, this digital block is not part of the described work.

External part
This field is not applicable for the specific application (see: General overview, above).

Communication scheme
This field is not applicable for the specific application (see: General overview, above).

Electromechanical specifications
For validation purposes, the above described QRS-complex detector has been implemented in the bipolar, semi-custom IC process SIC3A (Delft University of technology) with an operating voltage of 2 V. The total power consumption per scale (α) is equal to 55 nW, thus, for the current 5-scale implementation, an overall of 275 nW is required. No information is given on IC dimensions.

2.3 Some interesting cases

This survey will be concluded with a few papers discussing some special topics. Strictly speaking, these do not describe implantable systems as the ones discussed above, yet, are considered important achievements in the field since they can contribute to the further progress of such systems. The specifics are discussed in the next subsections.

2.3.1 Near-infrared light power/information transmission for implantable medical devices (Goto et al., 2001) [26, 25, 45]

So far, we have seen implants that can be powered andcommunicated by inductive RF links. Goto et al. propose two new devices for power supply and information transmission regarding implantable medical devices. Both devices are based on a technique for transcutaneous power supply using near-infrared light [45]. This is a non-invasive technique but, opposite to RF links, near-infrared links cause little electromagnetic disturbances for surrounding instruments.

The implantable power supplier consists of an array of PIN photodiodes (total detection area: 2.1 cm^2) and a rechargeable battery (capacity: 100 mAh). If a near-infrared laser beam is illuminated to the array, the battery is being charged. By shining a laser beam of power density equal to 13 mW/cm^2 for 17 minutes, the battery is effectively charged with a constant 0.5 mAh at $3V$. This charge is considered adequate for powering a commercial pacemaker for 24 hours.

The implantable transmitter also consists of a PIN-photodiode array, a near-infrared LED and a phase-modulation circuit. By receiving (external) intensity-modulated laser light, the array generates power for the implant circuitry and a specific carrier wave. The carrier wave is, then, modulated according to a monitored (desired) bio-signal and transmitted out with the LED.

Both systems have been tested for efficient power and data transfer using actual biological samples (chicken tissue, 3 mm thick). The authors propose these techniques as suitable modules for a number of medical implant applications.

2.3.2 A TinyOS-based wireless neural interface (Farshchi et al., 2004) [20]

The following system is not implantable but, rather, externally mountable and designed for EEG telemetry of untethered animals. It is included in this study due to the originality of its approach, which overlays a neural interface upon a TinyOS-based sensing and telemetry platform.

Brain-wave activity, manifested as slowly- (1 Hz) or fast- (100 Hz) varying electrical impulses in the neurons, has been correlated to specific physiological outcomes such as sleep, excitation and epilepsy. In order to quantify brain activity, EEG can be recorded in or on the brain region of interest. Although EEG recordings are frequently performed as acute experiments (e.g. less than 6 hours), some studies require chronic or longer-term measurements. For example, the study of epilepsy requires continuous recordings to be made over a period of several days. To facilitate for such measurements, wireless neural recordings need to be used. In this context, the authors have developed a telemetry, miniature (but non-implantable) device for simultaneous, multichannel EEG recordings from freely moving subjects which can wirelessly transmit data to an external computer station or over the internet.

The authors position themselves in the middle of two trends in the field: the fully-custom, micromachined CMOS ICs and the off-the-shelf approaches which utilize chipsets of scaled-down, commercial components. In so doing, they attempt to combine benefits from both approaches: small size and ultra low power consumption from the former and reduced development times and cutting-edge features from the latter.

The described system consists of the miniature neural interface that can be attached to the monitored subject and an external module which receives EEG readouts wirelessly and either forwards them to a computer for further processing and display or transmits them over the internet through an internet gateway. It is stressed once more that the described system does not strictly comply with the context of this manuscript since it is not an implantable (i.e. in-vivo) device, nonetheless it is included in this study for the originality of its approach (to be discussed below) and for completeness purposes.

Functionality of the involved components of the system is based on an embedded operating system (OS), running underneath. The TinyOS relies on a component-based runtime environment designed to provide support to embedded systems with a minimal amount of physical hardware so as to keep the system size very small. The primary goal of utilizing this OS is to lead to ultra-low-power, miniature, wireless sensor devices (called "motes") that can be widely distributed in mesh networks

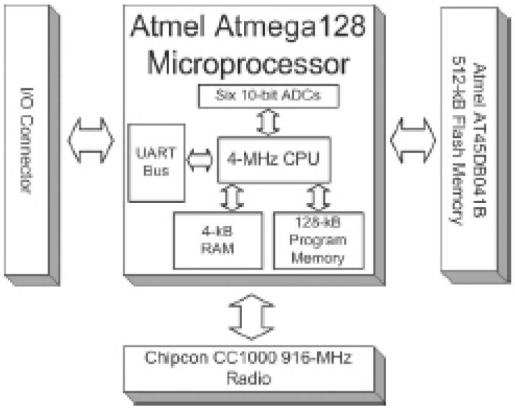

Figure 2.45: *System-level schematic of the MICA2DOT mote.*

(also known as "multi-hop networks") to remotely monitor low-frequency phenomena.

For the neural-interface device, a mote (MICA2DOT, Crossbow Technology Inc.) has been used which is built around an mC (Atmel ATMega128) with 512 kbytes of off-chip FLASH program memory and operating at a core frequency of 4 MHz (see Fig.2.45. In the current setup, the mote supports 2 EEG channels, each sensed differentially by a pair of electrodes externally connected to the mote. EEG-signal frequencies of up to 240 Hz can be detected, a figure which is considered adequate for neural potentials. A neural preamplifier circuit with a gain of 200 is used to take the differential signals and amplify, level-shift and convert them into to a single-ended waveform ranging from 0 V to (nominally) 3 V. This preamplifier circuit has been designed to interface directly with the mote. The heart of the neural preamplifier is an instrumentation amplifier (AD627, Analog Devices). To avoid HF-noise from being aliased into the sampled signal, the AD627 output is followed by an LP-filter. After conditioning, each EEG signal is fed into a 10-bit, on-chip ADC. Data transmission to and from the mote is handled by a radio chip (Chipcon CC1000) which FSK-modulates data on a $916-MHz$ carrier frequency. In the program memory of the mC, TinyOS-based software components have been written to implement data-acquisition and wireless media-access control (MAC) protocols for the mote. The data-acquisition component implements a two-channel, signal-acquisition and packetization algorithm to maximize data throughput while maintaining acceptable data resolution. The MAC protocols have been adjusted to allow for greater data throughput.

A second mote device (MICA2, Crossbow Technology Inc.) is used on the receiver end to remotely pick the transmitted EEG data. Structurally, it is essentially the same with the MICA2DOT mote but with larger (relaxed) dimensions and utilizes the same radio chip as the MICA2DOT for data reception. An MIB510 serial PC interface (implemented as a hardware interface board) is used to allow this second mote to further communicate with a PC. In addition, an MIB600 ethernet interface can also be used to broadcast sensor readings directly over the Internet. A Java-based program has been designed for use on the client PC. This program acquires data from a TCP/IP port and displays them either as raw data points or a reconstructed waveform. Signal reconstruction is performed by padding the original signal and passing it through an 8^{th}-order Chebyshev filter. Overall system throughput is 480, 8-bit samples/sec.

Communication between the two motes is achieved by developing TinyOS-based MAC protocols, specialized for high data throughput at low power rates. On the physical layer, FSM modulation of data is performed on an RF carrier signal. No further details are given on the communication specifics.

For an implementation with 2 data channels, a MICA2DOT mote has dissipated a maximum of 150 mW (@ 3 V). The MICA2DOT measures a diameter of 25 mm and a thickness of 6 mm and weighs (with battery) 12.8 g. The MICA2 measures 58 mm $\times$ 32 mm $\times$ 15 mm. Two 1.5-V dry-cell batteries (for a total of 3 V) have been used. The proposed system has been tested in vitro and in vivo (on living mice) and gave clear EEG waveforms revealing normal or seizure activity.

2.4 Chapter summary

In this chapter, more than 60 specific implantable systems have been reported. Information has been supplied on their internal structure, external-host organization, communication means, performance and physical characteristics. In the end, few additional cases have been included which are not actual implantable systems, yet constitute interesting approaches in the direction of miniature, micro-power systems.

Classification of microelectronic implants

3

3.1 Introduction

The previous chapter has made it obvious that current implementations of biomedical implants feature a multitude of attributes depending on the specific application field. Furthermore, designs are constantly being improved and enhanced due to the rapid evolutionary trends of microelectronics and micromachining in general. In this chapter, we attempt a classification of the described systems in various categories, based on a large set of attributes. Elaborate tables are given in order to present a clear view of the current state of things. Lastly, this classification will be used to extract observations and conclusions as drawn from the accumulated data.

3.2 Classification specifics

The existence of so many diverse attributes in the studied biomedical implants, makes their classification far from trivial. Effort is spent on taking into consideration as many of these attributes as possible while at the same time keeping complexity low. To this end, a two-level hierarchical classification of data has been designed. On the top level, eight major categories have been identified covering many aspects of an implantable system. On the second level, six of these categories have been further broken down, each into a set of related parameters considered to be the most important ones for our study. In detail, the eight major categories are described as follows:

i. ***APPLICATION***: refers to the medical problem the specific implantable system is designed to remedy. Intensive-care continuous monitoring, pain therapy, disease diagnosis, restoration of paralyzed limbs are a typical applications.

ii. ***FUNCTIONALITY***: refers to the functional principles employed by the implantable system for fulfilling its application purpose. This can typically be sensor-based acquisition of biological data or electrical stimulation of living tissue.

iii. ***ELECTROMECHANICAL FEATURES***: addresses the design approach and implementation technology of its microelectronic parts and packaging as well as the mechanical aspects of the implantable system, such as physical size.

iv. ***POWER FEATURES***: refers to the power consumption of the implant, to the power source used and to any implemented special features for low power.

v. ***GENERAL IMPLANT FEATURES***: refers to the most common attributes of microelectronic implants such as supported number and type of sensors and

actuators, provision for internal data storage (for data-acquisition systems), supported sampling rate, ADC or DAC resolution and other.

vi. ***PROCESSING/CONTROLLING-CORE FEATURES***: addresses further and more involved details of the processing/controlling core (if present) of the implant. Examples are the core frequency and the instruction-word and data-word sizes.

vii. ***MISCELLANEOUS IMPLANT FEATURES***: pertains to more specific attributes of an implant; for instance, to its ability to support various parameter settings, to support different peripheral modules (e.g. sensors), to feature hardware- or software-supported error handling during operation and other.

viii. ***COMMUNICATION FEATURES***: refers to the characteristics of the wireless communication (if present) between the implantable device and an external host. This category is divided into two major parts, the parameters of the incoming data flow (host to implant) and the parameters of the outgoing data flow (implant to host). Encoding and modulation techniques are discussed here as well as any implemented error handling scheme for achieving reliable communication.

From the above list of studied categories, it is obvious that the attempted classification includes attributes almost exclusively of the implanted components of the described systems but not of the external ones. External components have diverse features of their own and present their own challenges (as presented in the previous chapter), however, they do not come under the tight constraints or requirements their implanted counterparts do. Moreover, the concern in this document resides mainly on the characteristics of the central Processing/Controlling Core (PCC) that, if present, is implementing or - at a minimum - supporting the functionality of the implant. In this document, the terms "PCC" and "core" shall henceforth be used interchangeably referring to the same item, unless otherwise stated. Additionally, commonly met components in implantable systems such as sensors, actuators, electrodes and even wireless-communication modules shall also be collectively referred to as "peripheral units", "peripheral modules" or, simply, "peripherals". Finally, for preserving a consistent terminology, the eight categories shall appear throughout the text in capital letters whereas the underlying parameters shall appear in small letters, both in *italic* fonts.

In what follows, the reported parameters of each major category are analytically presented and their scope is clearly delineated. It is noted that for the first two categories, i.e. *APPLICATION*and *FUNCTIONALITY* no underlying parameters exist. For the remaining six categories the parameters are as follows:

ELECTROMECHANICAL FEATURES

1. ***PCC IC count***: this implies the number of ICs in the implant that are dedicated for control and/or processing functions. A zero value indicates an implant with non-centralized (or non-existing) processing and/or controlling core(s).

2. ***PCC design***: this holds the design style (full-custom, semi-custom or based on commercial, off-the-shelf components) of the PCC IC(s) (see above) in the implant. This field is meaningless if the "PCC IC count" parameter equals zero and is, in such cases, marked as "non-applicable".

3. ***PCC type***: this holds the type of design (digital, analog or mixed-signal) of the PCC IC(s) (see above) in the implant. This field is meaningless if the "PCC IC count" parameter equals zero and is, in such cases, marked as "non-applicable".

4. ***total chip(set) area***: this holds the area in mm^2 of the PCC chip(s) and/or of the overall implant chipset in case of discrete-component or multi-chip implementation. If more dimension figures are given (e.g. PCC area and total PCB area), all are reported and distinguished in this field.

5. ***package volume***: this holds the dimensions in mm^3 of the implant packaging.

6. ***total weight***: this is the total implant weight in g.

7. ***total transistor count***: this is the total number of CMOS transistors of the implant IC(s).

8. ***fabrication technology***: this is the fabrication process used for implant-IC(s) realization.

POWER FEATURES

1. ***power source***: it is the power source used in the implantable device.

2. ***power - digital***: the power consumption of the digital or mixed-signal PCC components of the design. A zero value indicates a design with no PCC(s).

3. ***power - total***: this is the overall power consumption of the implant.

4. ***low-power mode***: it refers to the special provisions in hardware and/or software of the implant for achieving low-power modes of operation (e.g. sleep mode).

GENERAL IMPLANT FEATURES

1. ***I/O (architecture)***: this is the complete set of peripherals (stimulating/monitring electrodes, sensors, actuators etc.) supported by the proposed architecture.

2. ***I/O (implementation)***: this is the set of peripherals (stimulating/monitring electrodes, sensors, actuators etc.) implemented in the currently described instance of the architecture. System power consumption, chip area, sample rates etc. that are given, obviously refer to the specific implant instance.

3. ***internal processing***: this refers to the ability of the core (if present), to perform not typical signal conditioning operations such as ADC/DAC, filtering etc., but further data manipulation, e.g. Fourier transformation, data compression, algorithms etc..

4. ***internal data storage***: this hints whether the implant has the ability to store measured biological data internally, i.e. in some internal memory block.

5. ***sampling rate***: this is the sampling rate in Hz supported by the implanted system when/if biological-data acquisition is performed.

6. ***ADC resolution***: this holds the resolution in *bits* of the included ADC(s) in an implant.

7. ***DAC resolution***: this holds the resolution in *bits* of the included DAC(s) in an implant.

PROCESSING/CONTROLLING-CORE FEATURES

1. ***PCC architecture***: it details the structural nature of the implant PCC (if present). This can be a custom or commercial mC or mP, a simple FSM, a timer circuit or other.

2. ***PCC frequency***: this is the basic clock frequency in MHz of the PCC(s) (if present).

3. ***non-PCC timing***: if a PCC is present in the design, this field is non-applicable. If it is not present, this field holds the running frequency in kHz of the overall implant design (e.g. for the SC-circuitry).

4. ***number of instructions***: this is the number of available instructions featured by the PCC. If the maximum number of instructions (as specified by e.g. the bits of the opcode) is also known, then it is also noted in brackets right next to the first number.

5. ***instruction-word size***: the size of instructions in *bits* of the core (if present) is implied. If the core only decodes external (telemetry) instructions and does not have an ISA of its own, this size coincides with that of the instruction-words (telemetry) - see below.

6. ***data-word size***: the size of data words in *bits* of the core (if present) is implied. Since many designs are highly customized, it may happen that this figure does not coincide with the instruction-word size. In cases where internal memory is included in the implant, this size is typically equal to the memory width.

MISCELLANEOUS IMPLANT FEATURES

1. ***adjustability***: it is the capacity of the implant to accommodate diverse operational settings (e.g. sample rate, filter bandwidth, amplifier gain, stimulus-pulse duration and amplitude, sensor sensitivity etc.) of its peripherals (e.g. sensors, actuators).

2. ***multiple-peripheral support***: refers to the ability of the implant to drive (within specific limits) different peripheral modules.

3. ***programmability***: it characterizes implants that include a program (and data) memory which executes specific downloaded code for achieving their functionality. This parameter does not refer to temporary data storage as e.g. is the case of FSMs where data are kept in registers for controlling the FSM state transitions. This parameter pertains to the ability of an implant to execute different source codes rather than some hardwired or hard-coded function.

4. ***modularity***: this refers to the design nature of the PCC(s) (if present). It includes generically designed cores that can inherently (i.e. without modifications) support many different biomedical applications by allowing the plugging-in of a large (infinite, theoretically speaking) set of different peripherals.

5. ***HW/SW error handling***: this includes all possible measures implemented in an implant design (either in hardware or in software) to perform handling of operation errors. This handling may range from simple error detection to error correction or recovery techniques.

6. ***EMI-resistance***: it hints whether any measures have been taken on the design level (analog and/or digital circuitry) to make the implantable system tolerant to external ElectroMagnetic-Interference (EMI) phenomena.

COMMUNICATION FEATURES

1. ***multipoint-communication support***: it indicates an implant that can coexist with multiple identical implants in the vicinity. A numerical value in this field indicates the maximum number of supported implants.

2. ***communication direction***: it refers to the direction of flow of information (but not of power) in a wireless link. The item of reference is the implant, thus, "inwards" means incoming information to it, "outwards" means outgoing information to an external host and "bidirectional" means both events.

3. ***Rx-modulation scheme***: it defines the modulation technique used for (instruction) information signals transmitted to the implant (if applicable) by an external host.

4. ***Rx-carrier frequency***: this is the carrier frequency of the incoming (instruction) transmission from an external host to the implant.

5. ***command encoding scheme***: this is the encoding scheme used for representing an incoming (to the implant) digital information signal. In case of analog information transfer, this parameter has no meaning.

6. ***command-packet size***: the size of incoming packets to the implant is meant.

7. ***command rate***: the maximum supported transmission rate (unless otherwise noted)in $kbits/sec$ of the instructions from an external host to the implant is given.

8. ***Tx-modulation scheme***: the carrier frequency of the outgoing data transmission from an implant to the external host (if applicable). In case passive telemetry techniques such as impedance reflection are utilized, this field is marked also as "non-applicable" since the implant does not employ an ***active*** transmitter circuit but, rather, piggy-backs information on the incoming carrier by modulating the inductive-link characteristics.

9. ***Tx-carrier frequency***: this is the carrier frequency of the outgoing data transmission from the implant to an external host. In cases where passive telemetry techniques are employed, this field is marked as zero since the implant includes no active transmitter. The only active transmitter is the one from the external host and this is the reason the field "in - carrier frequency" (seen before) is, in such cases, non-zero (since it contains the external transmitter carrier frequency).

10. ***data encoding scheme***: this is the encoding scheme used for representing an outgoing (to the external host) digital information signal. In case of analog information transfer, this parameter has no meaning.

11. ***data-packet size***: size of outgoing packets to the external host(s) is implied.

12. ***data rate***: the maximum supported transmission rate (unless otherwise noted)in $kbits/sec$ of the data packets from the implant is given.

13. ***communication error handling***: this contains all schemes implemented in an implant (usually in a specialized telemetry module) for handling over-the-air transmission errors. Such schemes may range from error detection (e.g. parity bit) to elaborate handshaking protocols for ensuring error-free (and, thus, safe) information exchange between the the implant and any external host(s).

3.3 Classification ground rules

For creating classification tables with the gathered data, a set of ground rules has been established and followed throughout, so as to make the classification as fair and consistent as possible. This is not a trivial task since many researchers fail to specify or are vague about particular aspects of their implementations. These ground rules come to complete or further disambiguate the meaning and scope of some of the above discussed parameters and their combinations.

It is often the case in filling in the data that no information is given on a specific implant trait or that the specific trait is meaningless (non-applicable) in the context of a specific implantable system. As far as table terminology is concerned, a non-reported piece of information is marked with a single dash line ("-") whereas a non-present or non-applicable field is marked with a "no" statement. For instance, if the field *communication direction* is marked as "inwards", implying strictly incoming flow of data to the implant, then the fields *out-modulation*, *data-packet size* etc. are automatically marked as "no" since there is no outgoing data flow to an external host.

There are cases where researchers have come up with consecutive, improved or simply modified versions of implantable systems over the years. While these versions are discussed in detail in chapter 2, they are not included in the classification tables. Rather, the latest version of a system is always reported. Exceptions to the above rule are few cases where one (older) version of an implantable system is so different in settings or design from the reported (latest) version that it is deemed noteworthy and included in the tables with an incremented number in brackets next to the author name - see, for instance, Sawan et al., Sawan et al. (2) etc..

Some included implants are designed for large animal implantation in husbandry and - while the principles of design and function are exactly the same as for human subjects - the physical-size constraints can be somewhat relaxed due to the comparatively larger body mass of the targeted subjects (e.g. cows). Therefore, an increased *total chip(set) area* or *package volume* should not be of surprise.

For the *PCC architecture* field (category: *PROCESSING/CONTROLLING-CORE FEATURES*), confusion might be created to the reader in cases where a PCC is reported as "FSM" while, at the same time, in the corresponding published paper it is reported as "mP" or "mC". This is purposefully so for remedying the bad terminology on the part of the paper authors: in such cases their implemented control is a state machine or simple timer circuit which adopts processing and/or controlling tasks for the implant, e.g. command decoding, data forwarding, state transition etc.. Even though this constitutes the control logic for the whole implant, it can under no circumstance be called an mP or mC (even if peripherals are driven by this logic). For keeping a consistent classification, implicit checks and corrections (where needed) have been made throughout the tables.

Another issue considering the PCC(s) of an implant is the following: in case a commercial, off-the-shelf mC or mP is utilized as the PCC, the instruction- and data-word sizes are set equal to the architecture of the PCC in our classification. For instance, an 8-bit RISC mC shall signify 8-bit instruction and data words, since these are the quantities that "move around" inside the implant core.

Instruction/data-word sizes (category: *PROCESSING/CONTROLLING-CORE FEATURES*) and command/data-payload sizes (category: *COMMUNICATION FEATURES*) are often reported as e.g. `"1+2+13"` to roughly sketch the underlying packet structure. For the given example, a specific meaning could be: `"1 start bit, 2 parity bits, 13 data bits"`. There are also cases (only in communication packages) where something like `"sync+1+2+13"` is reported. The extra `"sync"` term implies the existence of a sync pulse (usually a multiple of a single bit duration) preceding the actual bit stream.

In some of the considered implantable systems, the authors state that "the proposed system can with minor modifications be used for other applications". If this is the case, such systems are not considered to be of modular design. In order for the

modularity field to be marked as positive, a PCC must be able to inherently implement a theoretically infinite number of system setups, that is, to be able to support different applications without redesigning the PCC in part or in whole.

It is stressed that all communication-related parameters (category: *COMMUNICATION FEATURES*) refer strictly to the interface between the implant and the first external host module of a system, if more than one external stage is included in the design. For instance, in an implant-backpack-workstation setup (2-stage), the reported interface in the tables is only the one between the implant and the backpack. The reason for this policy is obvious: the critical implant design constraints - which are the concern of this document - affect only this very first interface between the implant and the outside world. The remaining parts of the external subsystem are of little consequence.

A case that may also cause confusion is when an implant processes or transmits fully analog information. Then, fields such as *data-packet size*, *data rate*, *sampling rate* etc. will be termed as non-applicable since they refer to digitally-coded information even though fields such as *Rx-modulation scheme* and *Rx-carrier frequency* are filled.

Furthermore, it should be stressed that various figures reported in the classification tables, refer to the specific implant instance described in a published paper. For instance, in case a system can maximally support e.g. 4 measurement channels (*I/O (architecture)*) but in the described implementation it incorporates a subset of them, e.g. only 2 (*I/O (implementation)*), the *power consumption* and *sampling rate* of the implant refer to the 2-channel setup. If information for more than a specific setup of the implant are given, they are clearly included in the tables.

As a last remark, if - all the above rules considered - some combinations of data entries in specific rows of the following tables seem irrational, there is probably a good explanation for it. Thus, the reader is advised to refer to the corresponding abstract(s) of the previous chapter for further clarification.

3.4 Tables and conclusions

The classification tables are presented in this section. Due to their excessive size (many study cases, many parameters), information has been segmented vertically in smaller tables, according to the general categories, and horizontally, in two bundles of 20 and 21 papers, respectively. For the *WIRELESS COMMUNICATION FEATURES*, the table has been vertically split further in two subtables - one mainly containing the incoming flow and one mainly the outgoing flow.

3.4.1 Application & Functionality

In what follows, the tables are drawn, each followed by various comments and observations considering the specific table data, so as to make navigation through this bulk of information as smooth as possible. The categories *APPLICATION* and

FUNCTIONALITY are displayed in the tables 3.1 and 3.2.

The *APPLICATION* column, readily displays the wide spreading of implantable devices over diverse medical fields. One of the most frequently encountered implant applications is cardiac pacing and defibrillation for treating cases of cardiac arrhythmia. Actually, the pacing implants are the famous pacemakers which are also the first microelectronic devices to have ever been implanted into a human. These devices are principally the same as the first pacemaker that was implanted 50 or more years ago. Since then, they have come a long way and now - in their fourth generation - encompass a multitude of features and have a battery life expectancy of almost 10 years.

System	Publication Year	Application	Functionality
Mouine et al. [44]	2000	pain therapy	stimulation
Enokawa et al. [19]	1997	RSNA, ECG	measurement
Flick et al. [23]	2000	ICP-based diagnosis for brain diseases	measurement
Eggers et al. [18]	2000	ICP-based diagnosis for brain diseases	measurement
Min et al. [43,43]	2001	body response to tissue / organ transplantation	measurement
Sears et al. [61]	1999	performance of implanted artificial heart-valve	measurement
Beach et al. [8]	2001	tissue response to implanted devices	measurement
Huang et al. [33]	1998	physiological parameters (here: temperature)	measurement
Kawahito et al. [34]	1994	physiological parameters (here: ECG, EMG)	measurement
Rorie et al. [55]	1996	physiological parameters (here: orthopaedic implant stresses)	measurement
Coggins et al. [14,15]	1995	proper ICD pacing / shock therapy	classification
Wouters et al. [71]	1994	physiological parameters (here: temperature, movement (for animals))	measurement
Shawkey et al. [62]	1998	proper ICD pacing / shock therapy	classification
Nardin et al. [47]	1995	restoration of paralyzed-muscle functionality	stimulation
Harpster et al. [30]	2000	hermeticity of implant packaging	measurement
Lerch et al. [38]	1995	physiological parameters (here: ECG, heart-muscle elasticity, electrolyte-composition data of transplanted hearts)	measurement
Akin et al. [1,2]	1994	neural-activity study (for better control of prosthetic devices)	measurement
Rollins et al. [54]	2000	continuous ECG for understanding spontaneous cardiac arrhythmias	measurement
Shults et al. [63]	1994	blood-glucose level detection for diabetic patients	measurement
Sawan et al. [60]	1996	bladder control for complete evacuation	stimulation
Sawan et al. (2) [58]	1989	bladder control for complete evacuation	stimulation

Table 3.1: Implant application and functionality.

Other commonly encountered implant applications are in-vivo electrocardiography (ECG), electroencephalography (EEG) and electromyography (EMG). Modern implants display a largely electronic nature which has been an excellent substrate for developing this kind of electricity-based measurements. Additionally, their miniature size has allowed researchers to build minimally invasive systems. Moreover, measured-signal distortions due to e.g. electrodes penetrating the skin (conductive medium) have been averted, resulting in precise, low-noise measurements. To give an idea about the popularity of this class of applications, 9 such implants in a total of 41 have been

encountered. Following the above mentioned biological quantities, also popular are other in-vivo measurements such as temperature, intracranial pressure (ICP), biopotentials, tissue bio-impedance and gastric pressure.

System	Publi-cation Year	Application	Functionality
Sawan et al. (3) [56,59,57]	1996	bladder/micturition control for complete evacuation	stimulation
Smith et al. [64]	1998	restoration of paralyzed-muscle functionality, MES	stimulation / measurement
Clements et al. [12,13]	1999	ocular restoration	stimulation
Park J. et al. [51]	1994	physiological parameters (here: pressure, temperature, pH, biopotentials, ECG, EMG)	measurement
Pramassing et al. [53]	2000	ocular restoration	stimulation
Lande et al. [36]	2000	auditory restoration	stimulation
Atanasov et al. [5,4,9]	1997	blood-glucose level detection for diabetic patients	measurement
Kettlewell et al. [35]	1997	ECG, temperature, respiratory movement	measurement
Beach et al. (2) [6,7]	1999	blood-glucose level detection for diabetic patients	measurement
Wei et al. [70]	1995	pain therapy	stimulation
Parramon et al. [52]	1997	EMG	measurement
McCreesh et al. [40,39]	1994	temperature-based ovulation detection for natural contraception and in-vitro fertilization	measurement
Valdastri et al. [69]	2004	gastric pressure	measurement
Fernald et al. [21,16,22]	1991	physiological-parameter measurement (sensors) / influence (actuators) (here: measurement of biopotentials)	generic function
Harrigal et al. [31]	1990	pacemaker, ECG	stimulation / measurement
D'Lima et al. [17,66,68,67]	2005	intra-articular tibial-force study (for better design of rehabilitation devices)	measurement
Park H.J. et al. [49,50,37]	2003	endoscopy	measurement
Harrigal et al. (2) [32]	1992	vocal restoration	stimulation / measurement
Von Arx et al. [3]	1999	neural stimulation (exact purpose not given)	stimulation
Haddad et al. [27,28]	2003	proper ICD pacing / shock therapy	classification

Table 3.2: Implant application and functionality (continued).

A physiological parameter that has received a lot of attention, and is present in this study, is detection of glucose levels in the blood. This is a hot topic these days given the large (and increasing) number of diabetic patients worldwide. High glucose levels (hyperglycemia) in the blood stimulate the pancreas for releasing insulin to lower glucose concentration. Since in diabetic patients the pancreas cannot produce insulin, an "artificial pancreas" is required, virtually a closed-loop control system which will probe the glucose levels in the blood stream and release insulin as required. Glucose-level sensing implants constitute only half of this control circle, the other half being drawn by implantable micropumps for administering insulin. Even though the design of an actual, working, artificial pancreas has not been achieved yet, since there are a lot of issues that remain unsolved, the glucose-sensing implants have constantly increased in numbers and improved over the years.

In a different direction, a medical field that has been enriched with many research efforts over the years is the electrically stimulated restoration of various body functions. Nerve

and muscle stimulation has been attempted for restoration of limb movement, hand grasp, micturition and bladder control, eyesight and hearing and other. Stimulation has also been used as pain therapy by chronic-pain patients for interrupting nerve (pain) signals from the spinal cord to the brain. As an indication of the popularity of the aforementioned field, 13 out of 41 such devices are present in the tables. Obviously, this high percentage is again somewhat biased since microelectronic devices are considered excellent vehicles for delivering stimulating electrical pulses inside the human body.

From the above, and also by studying the *FUNCTIONALITY* tables it comes as no surprise that measurement and stimulation are the two dominating implant functions encountered these days (Fig.3.1). This also makes perfect sense given the microelectronic nature of the studied devices. Obviously, different functionalities also exist, like the micropump - discussed above - which is based on micromachined components (MEMS), but are of no further concern to this document.

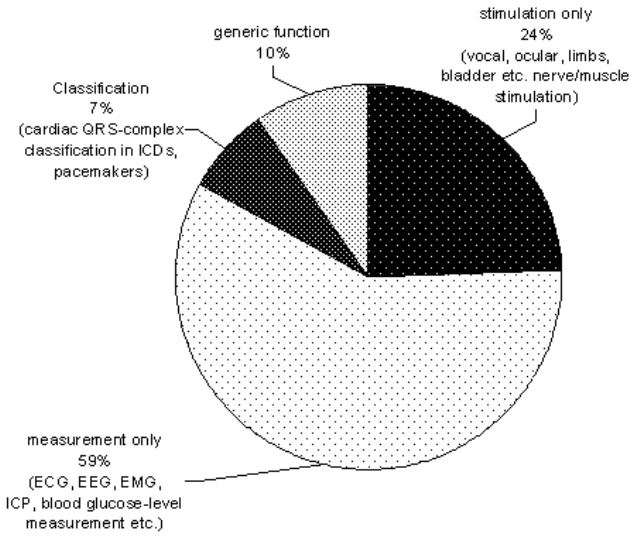

Figure 3.1: Distribution of implant functions.

As a last remark for the above tables, it is noted that - with the exception of the pacemaker and few other systems - most of the above discussed families of implantable systems have not widely penetrated the medical market. Even devices that are fully miniaturized and properly packaged for implantation seem to have remained simple prototypes in a lab bench. The reasons to this situation are varied (for instance, unsatisfactory chronic in-vivo behavior of packaging materials) but it - too - is not the goal of this document to analyze them. Suffice to say though, this situation does not affect our discussion here or any extracted conclusions.

3.4.2 Electromechanical features

For the category *ELECTROMECHANICAL FEATURES*, tables 3.3 and 3.4 are constructed. Proposed implantable devices are most commonly built around some form of central processing and/or controlling unit - the above discussed PCC. Most often, implemented PCCs are full-custom designs incorporating mixed-signal circuitry. The full-custom nature is justified by the fact that most stringent design constraints need to be squeezed in as little circuit area as possible, thus, not allowing the luxury

System	Publi-cation Year	Electromechanical features							
		PCC IC count	PCC design	PCC type	total chip(set) area (mm2)	package volume (mm3)	total weight (g)	total transistor count	fabrication technology
Mouine et al. [44]	2000	1	full-custom	mixed-signal	-	-	-	-	BiCMOS (0.8 µm)
Enokawa et al. [19]	1997	1	commercial	mixed-signal	40 × 35	15000	46	-	-
Flick et al. [23]	2000	0	no	no	6 × 28	6 × 28 × 2	-	-	CMOS
Eggers et al. [18]	2000	0	no	no	-	-	-	-	CMOS (0.7 µm)
Min et al. [43,43]	2001	0	no	no	-	-	-	-	CMOS (2 µm)
Sears et al. [61]	1999	1	commercial	mixed-signal	-	-	-	-	-
Beach et al. [8]	2001	0	no	no	-	31 × 54 × 28	-	-	-
Huang et al. [33]	1998	0	no	no	4 × 5	-	-	-	BiCMOS (2 µm, 40 V)
Kawahito et al. [34]	1994	1	full-custom	mixed-signal	5.1 × 5.1	-	-	600	CMOS (5 µm)
Rorie et al. [55]	1996	1	full-custom	digital	2.5 × 2.5	-	-	-	CMOS (0.8 µm)
Coggins et al. [14,15]	1995	1	full-custom	analog	2.2 × 2.2	-	-	-	CMOS (1.2 µm)
Wouters et al. [71]	1994	2	semi-custom	mixed-signal	9.97 × 2.68 (SIC) 9.97 × 2.68 (mP)	40 × 5 (cylin)	-	-	CMOS (2 µm, n-well)
Shawkey et al. [62]	1998	1	full-custom	analog	-	-	-	-	CMOS
Nardin et al. [47]	1995	1	full-custom	mixed-signal	-	1.4 × 13.5 (cylin)	-	2800	BiCMOS (3 µm, 2-poly, 1-metal)
Harpster et al. [30]	2000	0	no	no	-	7 × 1.2 × 1.5	-	-	-
Lerch et al. [38]	1995	1	full-custom	mixed-signal	85.4	-	-	70000 (dig) 5000 (an)	CMOS (1.5 µm)
Akin et al. [1,2]	1994	1	full-custom	digital	4 × 6	5 × 8 × 2	-	> 5000	BiCMOS (3 µm, p-well, 2-poly, 1-metal)
Rollins et al. [54]	2000	1	stuctured custom	mixed-signal	73.66 × 57.15	78.74 × 76.20 × 22.86	-	-	-
Shults et al. [63]	1994	0	full-custom	analog	25 × 63	12 × 32 × 70	27	-	-
Sawan et al. [60]	1996	1	structured custom	mixed-signal	35 (cycl)	-	-	-	-
Sawan et al. (2) [58]	1989	1	full-custom	mixed-signal	4.51 × 4.51	-	-	12753	CMOS (3 µm)

Table 3.3: Implant Electromechanical features.

of component-based design. Power is an additional attribute that usually benefits from full-custom design since implementations tend to have lower power requirements compared to ones based on off-the-shelf components. Small size also benefits from the mixed-signal approach used since integrated analog and digital circuitry takes up less space than discrete (analog) components.

These trends in implant design seem to be confirmed by the data collected in the tables. More specifically, 28 of 41 (68%) studied implants include some kind of PCC. Of these 28 devices, the *PCC design* is broken down as follows: 3 commercial (11%), 2 semi-custom (7%) and 23 full-custom or structured custom (82%) designs. Furthermore, of the 28 devices, 3 are analog (11%), 12 are digital (43%) and 13 are mixed-signal (46%) designs. These results are visualized in Fig.3.2 and Fig.3.3. An additional observation is that the implant control is indeed centralized with all PCC-enabled devices (except for one) realizing a single PCC unit (the exception featuring two units in master-slave connection).

The *fabrication technology* used is almost with no exception either CMOS or BiCMOS. The reason is rather obvious: CMOS technology features very high integration, low power consumption and large noise margins, all highly suited for biomedical-implant applications. Further, bipolar CMOS (BiCMOS) is especially used by many researchers to construct mixed-signal devices. Apart from the standard CMOS attributes, BiCMOS also offer large current-driving capabilities (very important, for instance, for implantable stimulators) as well as intrinsic protection (e.g. integrated Zener diodes) for the implant electronics from accidental or steady-state high-voltage inputs.

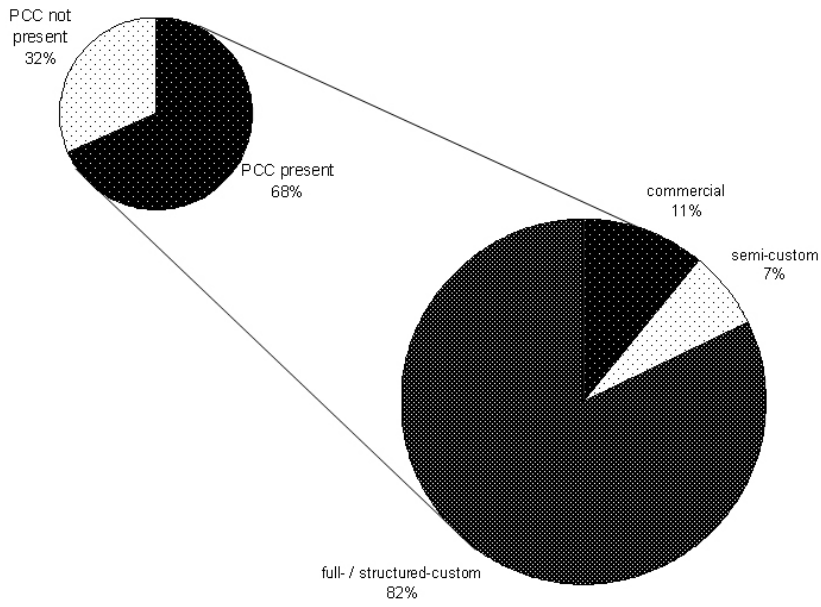

Figure 3.2: Distribution of PCC design styles.

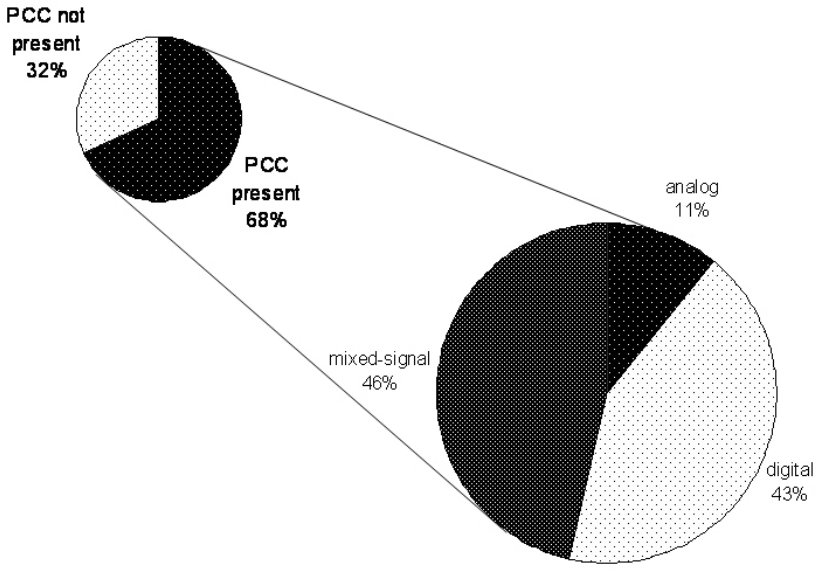

Figure 3.3: Distribution of PCC design approaches.

The λ factor used in the CMOS or BiCMOS designs in many cases does not appear to follow the market trend. These devices are highly customized and the researchers appear to have used per case the fabrication technology available to them and not necessarily the state of the art (at the publication time). Even so, it appears that in order to develop reliable devices targeted for medical use, they have often preferred a stable (at the time) process technology, i.e. a technology some steps behind the then top fabrication process. Roughly speaking, designs have gradually scaled down during the 90s from 5 μm to 3 μm, 1.2 μm and even to 0.6 μm. The same case appears for other mechanical and physical considerations of the devices, i.e. *total chip(set) area*,

System	Publi-cation Year	Electromechanical features							
		PCC IC count	PCC design	PCC type	total chip(set) area (mm2)	package volume (mm3)	total weight (g)	total transistor count	fabrication technology
Sawan et al. (3) [56,59,57]	1996	1	structured custom	mixed-signal	6 × 6 (FPGA) 22 (cycl PCB)	-	-	2000 gates (FPGA)	CMOS (4 µm)
Smith et al. [64]	1998	1	full-custom	mixed-signal	25 × 37.5	100 × 45 × 10	60	-	CMOS (1.2 µm, n-well)
Clements et al. [12,13]	1999	1	full-custom	digital	4.6 × 4.7	-	-	-	CMOS (1.2 µm)
Park J. et al. [51]	1994	0	no	no	4 × 4	-	-	-	CMOS (1.5 µm)
Pramassing et al. [53]	2000	1	custom (not specified)	digital	-	-	-	-	CMOS (0.6 µm, n-well)
Lande et al. [36]	2000	1	full-custom	digital	-	-	-	3000	CMOS
Atanasov et al. [5,4,9]	1997	0	no	no	-	50 × 75 × 15	140	-	-
Kettlewell et al. [35]	1997	0	no	no	-	66 × 25 × 29	105	-	-
Beach et al. (2) [6,7]	1999	0	no	no	-	18 × 26 × 40 (PCB) 26 × 9 (cylin) (Puck)	-	-	CMOS
Wei et al. [70]	1995	1	full-custom	digital	-	-	-	-	CMOS (1.5 µm)
Parramon et al. [52]	1997	1	full-custom	digital	30	1000	-	-	BiCMOS (2.5 µm)
McCreesh et al. [40,39]	1994	0	no	no	10 (×2) (cycl)	18 × 60. (cylin)	-	-	-
Valdastri et al. [69]	2004	1	semi-custom	mixed-signal	18 × 9 × 5	19 × 27. (cylin)	-	-	-
Fernald et al. [21,16,22]	1991	1	full-custom	digital	-	-	-	-	CMOS
Harrigal et al. [31]	1990	1	full-custom	digital	-	-	-	-	CMOS (2 µm)
D'Lima et al. [17,66,68,67]	2005	1	commercial	digital	-	14.6 × 30.5 × 6.5	-	-	-
Park H.J. et al. [49,50,37]	2003	1	structured custom	digital	-	12 × 30 (cylin)	-	-	-
Harrigal et al. (2) [32]	1992	-	-	-	-	-	-	-	-
Von Arx et al. [3]	1999	1	full-custom	digital	2 × 8.7	-	-	3100	BiCMOS (3 µm, p-well, 2-poly)
Haddad et al. [27,28]	2003	0	no	no	-	-	-	-	semi-custom, bipolar IC (SIC3A)

Table 3.4: Implant Electromechanical features (continued).

total transistor count, *package volume* and *total weight*. It should be noted, though, that some of the described systems have been implemented as mere prototypes at the time of paper publication. In such cases, the fabrication technology used as well as physical size, weight etc. may not be representative of the actual implantable version of a system. This, along with the fact that many researchers very often fail to provide information about the above mentioned figures, makes generalization impossible.

3.4.3 Power features

Power consumption is of special concern to the design of implantable systems. Therefore, the power-related tables 3.5 and 3.6 are drawn separately. As seen in the tables, the implant *power source* is either an included miniature battery or an RF inductive link with an external host transmitter transferring (electromagnetic) power to the implant wirelessly, by emitting a carrier signal (Fig.3.4).

A fraction of this signal is captured and AC/DC-converted (rectified and smoothened) by the implant for generating a constant DC supply. The type of power source preferred by a research team, heavily depends on the implant volume constraints as well as on the life expectancy of the implanted system. For chronic implantation (i.e. more than a year) batteries are usually not suitable.

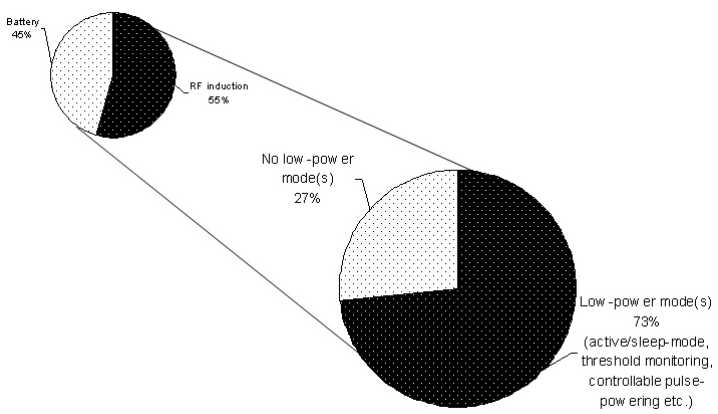

Figure 3.4: Distribution of implant power schemes.

An attempt has been made to distinguish between the power consumption of the digital and that of the analog part of each presented implant. However, as the corresponding tables show, this has not been possible in most of the cases since the researchers do not explicitly mention separate figures for those. Nonetheless, figures for total power consumption have been reported more often. An upper bound to the power consumption of all studied implants has been found to be approximately equal to 1000 mW. The average power consumption, though, is much lower; equal to approximately 165 mW. However, it should be noted that deviations in this column are large, ranging from minimalistic implants which only employ a sensing

System	Publication Year	Power features			
		power source	power - digital (mW)	power - total (mW)	low-power mode
Mouine et al. [44]	2000	RF induction	-	-	no
Enokawa et al. [19]	1997	RF induction	>> 10	>> 10	no
Flick et al. [23]	2000	RF induction	-	5	no
Eggers et al. [18]	2000	RF induction	-	0.35	no
Min et al. [43,43]	2001	-	0	0.01375	no
Sears et al. [61]	1999	-	500.045	> 500.045	-
Beach et al. [8]	2001	battery	0	1080	no
Huang et al. [33]	1998	RF induction	-	0.52	no
Kawahito et al. [34]	1994	battery	-	7.5	no
Rorie et al. [55]	1996	battery	-	-	yes
Coggins et al. [14,15]	1995	-	-	0.000186	-
Wouters et al. [71]	1994	battery	-	0.075 (monitorring), 12 (transmitting)	yes
Shawkey et al. [62]	1998	-	-	few mW	-
Nardin et al. [47]	1995	RF induction	-	40	no
Harpster et al. [30]	2000	RF induction	-	-	no
Lerch et al. [38]	1995	battery	-	3.9	yes
Akin et al. [1,2]	1994	RF induction	< 7.1	15	no
Rollins et al. [54]	2000	transdermal wiring (battery)	-	34	no
Shults et al. [63]	1994	battery	-	0.0392 (standby), 16.8 (transmitting)	yes
Sawan et al. [60]	1996	RF induction	-	-	no
Sawan et al. (2) [58]	1989	RF induction	-	-	no

Table 3.5: Implant power features.

element and simple, passive telemetry utilizing a few milliwatts, to more complex structures that perform varied tasks and utilize hundreds of milliwatts. This diversity in customized implementations and in application requirements makes it difficult to draw a conclusion about power consumption. Obviously, the power figures also depend heavily on the fabrication technology and on the number of transistors implementing the design. Unfortunately, the latter is not reported for the majority of the devices, complicating the power issue further.

A more implicit attribute affecting further power figures is the existence of any kind of *low-power mode* during implant operation. This is commonly seen in battery-powered implant realizations where prolongation of battery lifetime is of prime importance (Fig.3.4). Low-power states come in various flavors: interrupt-switchable sleep modes, controllable pulse-powering of implant subsystems depending on their functionality, firmware implementations of adjustable operational settings (e.g. sampling rate) when there is no need for maximum performance are typical examples of implemented low-power schemes.

System	Publi-cation Year	Power features			
		power source	power - digital (mW)	power - total (mW)	low-power mode
Sawan et al. (3) [56,59,57]	1996	RF induction	-	8	no
Smith et al. [64]	1998	RF induction	-	< 120	controllable pulse-powering of modules per case
Clements et al. [12,13]	1999	RF induction	-	3 (frame-rate: 100 Hz or 40 kbps)	no
Park J. et al. [51]	1994	battery		> 498	pulse-powering of implant selectively, time-out for power down
Pramassing et al. [53]	2000	RF induction	-	395	no
Lande et al. [36]	2000	-	-	< 0.5	-
Atanasov et al. [5,4,9]	1997	battery	-	-	yes
Kettlewell et al. [35]	1997	battery	-	-	-
Beach et al. (2) [6,7]	1999	battery	-	1.1248 (potentiostat) + telemetry-block	yes
Wei et al. [70]	1995	RF induction	-	-	no
Parramon et al. [52]	1997	RF induction	-	22.5	no
McCreesh et al. [40,39]	1994	battery	-	-	-
Valdastri et al. [69]	2004	battery	-	-	firmware implementation (active/sleep-mode, threshold-monitoring)
Fernald et al. [21,16,22]	1991	battery	-	-	active/sleep-mode
Harrigal et al. [31]	1990	battery	-	-	active/alert(low-power)-mode
D'Lima et al. [17,66,68,67]	2005	RF induction	-	9	no
Park H.J. et al. [49,50,37]	2003	battery	-	66	on-off switching of camera/LEDs
Harrigal et al. (2) [32]	1992	-	-	-	-
Von Arx et al. [3]	1999	RF induction	-	14.8 (stimulating) 6.28 (not stimulating)	no
Haddad et al. [27,28]	2003	-	-	0.000275	-

Table 3.6: Implant power features (continued).

Last but not least, in this category an additional parameter has been added during the initial steps of the study: power dissipation. This is the power emanating from an implant to its environment during operation and consists primarily of two components. The first one is the electromagnetic power dissipated in the tissue residing on the inductive-link path formed between the implant and external-host transceivers (in case of wireless power or data transfer). The second component stems from the function of microelectronics in the implant circuitry. The microelectronics dissipate thermal power which results in a temperature rise in the implant and - through thermal conduction - to the surrounding tissue. Both com-

ponents can be quantified with the tissue exposure index (in mW/cm^2) and are very crucial for characterizing the operation of an implantable device as harmless or potentially harmful for the carrier. Unfortunately, information on the issue has been scarce or scarcely supplied by most researchers (exceptions are Beach et al. [8] and Valdastri et al. [69]). Therefore, we have excluded it from the classification tables since no solid conclusions can be drawn.

3.4.4 General implant features

In this section tables 3.7 and 3.8 are included which contain information about features typically met in all implantable devices. The first two columns of these tables contain information about the I/O peripherals connected to an implant, i.e. any sensors, actuators, stimulating/measurement electrodes or other interface to the living tissue. A clear distinction is made between the maximal number and type of such peripherals that an implant architecture is designed to support and the actual number and type of peripherals included in the specific instance under study. Such a distinction is important, first and foremost, because all reported figures such as size, power consumption, packaging etc. refer to the specific (usually limited) instance of an architecture and not to a maximal setup. A second reason for making this distinction is for observing the practical limitations introduced in a design during actual implementation. An excellent paradigm of such a case is the generic system proposed by Smith et al. [64]. It is designed with the capacity to support 32 stimulation or sensor-feedback channels, 8 sensor telemetry channels, 8 processed-MES telemetry channels, 8 unprocessed-MES telemetry channels and 8 system telemetry channels. However, in the practical application of developing an implantable paralyzed-muscle stimulator based on the above described system, a version with the following peripherals has been finally implemented: 9 (motor) stimulation channels, 1 sensor feedback channel and 1 data-acquisition channel. Increased IC power consumption and area are minor limitations for implementing the full system. The bottleneck in the specific design would be to fit such a large number of contact pads on the IC and feed-throughs on the implant package for supporting the full set of I/O peripherals.

A last but equally important conclusion can be drawn from the I/O columns. It is made clear that implant developers struggle to equip systems with as many I/O peripherals as possible - save for the very area-restricted, minimalistic ones (e.g. for ICP measurement). Over the years, researchers have increasingly tried to squeeze inside the same implant the maximum number of peripherals simultaneously "permitted" by the design constraints. This observed trend agrees with the popular vision of future implants being tiny magic boxes able to perform a pleiad of measurements from or interventions to the organism.

The *internal processing* field refers to those implants that actually perform some kind of processing in their PCC (if present). As earlier stated, under the term "processing" we do not include any signal processing tasks common to almost all implants, such as data sampling, filtering, A/D-conversion, multiplexing or other. Rather, we wish to isolate

System	Publi-cation Year	General implant features						
		I/O (architecture)	I/O (implementation)	internal processing	internal data storage	sampling rate (Hz)	ADC resolution (bits)	DAC resolution (bits)
Mouine et al. [44]	2000	16 electrodes	-	no	no	no	no	3
Enokawa et al. [19]	1997	2 channels	2 channels: RSNA, ECG	no	no	2000	8	no
Flick et al. [23]	2000	2 sensors	2 sensors: pressure (capacitive), temperature (>>)	no	yes	40	no	no
Eggers et al. [18]	2000	1 sensor	1 sensor: pressure (capacitive)	sensor data reduction	no	100	10	no
Min et al. [43,43]	2001	2 channes	2 channels	no	no	50	no	no
Sears et al. [61]	1999	1 sensor	1 sensor: aortic flow (2 pressure transducers)	no	no	-	8	no
Beach et al. [8]	2001	1 sensor	1 sensor: tissue video (CCD camera)	no	no	no	no	no
Huang et al. [33]	1998	1 sensor	1 sensor: blood pressure (magneto-resistive bridge)	no	no	100	9	no
Kawahito et al. [34]	1994	2 channels	2 channels: ECG, EMG	no	no	4340000 (1ch/1sub, max) (here: 2170000, 2ch/2sub:)	no	no
Rorie et al. [55]	1996	4 sensors	4 sensors: orthpedic-implant stress (strain gauge)	no	yes	0 to 32000	-	no
Coggins et al. [14,15]	1995	1 channel	1 channel: ST / 1:1 VT discrimination	no	no	250	no	no
Wouters et al. [71]	1994	2 sensors	2 sensors: temperature (thermistor), movement (2 cap. accelerom.)	movement algorithm	yes	-	8	no
Shawkey et al. [62]	1998	1 channel	1 channel: ST / 1:1 VT discrimination	no	no	-	no	no
Nardin et al. [47]	1995	8 electrodes	4 electrodes	no	no	no	no	no
Harpster et al. [30]	2000	1 sensor	1 sensor: humidity (capacitive)	no	no	-	no	no
Lerch et al. [38]	1995	-	9 electrodes (ECG, electrolyte comp.), 2 wall-motion sensors (heart-muscle elasticity)	no	yes	-	8	no
Akin et al. [1,2]	1994	1 sieve electrode (up to 32 channels)	1 sieve electrode (up to 32 channels)	no	no	-	8	no
Rollins et al. [54]	2000	8 electrodes (+ casing as reference electrode)	8 electrodes (+ casing as reference electrode)	no	no	1000	12	no
Shults et al. [63]	1994	1 sensor	1 3-electrode glucose sensor	no	no	no	no	no
Sawan et al. [60]	1996	1 channel	1 channel	no	no	no	no	8
Sawan et al. (2) [58]	1989	8 electrodes	8 electrodes: 8 monopolar or 4 bipolar channels	no	no	no	no	5

Table 3.7: General implant features.

any extra processing schemes an implant core might perform, such as a 2-D motion detection algorithm based on readouts from two accelerometers (as seen in Wouters et al. [71]). Surprisingly, the set of such implants is not identical to the set of those that include - for instance - a real mC or mP core. Let us borrow some information from the *PCC architecture type* (category: *PROCESSING/CONTROLLING-CORE FEATURES*): only 3 out of 8 cores reported as mCs or mPs (FSMs and other simple control structures are not considered) appear to make actual use of the implant processing capabilities. By studying the implementations described in chapter 2, it turns out that most implant cores, even if bearing (programmable) processing capabilities, perform only basic tasks in the implant. The obvious reason for this phenomenon is that extra processing means extra power. So, even if an application could make good use of some sort of data manipulation inside the implant, designers prefer to telemeter the data to an external host system, have it process the data and even transmit results back to the implant for closed-loop control (see, for instance, Smith et al. [64]). In view of the rapid advances in CMOS technology which features ever increasing transistor operating frequencies at ever decreasing area and power cost, this phenomenon does not necessarily need to be so. Rather, more "high-level", intelligent or complex functionalities can now and in the near future be incorporated in implantable systems without significant effects

System	Publi-cation Year	General implant features						
		I/O (architecture)	I/O (implementation)	internal processing	internal data storage	sampling rate (Hz)	ADC resolution (bits)	DAC resolution (bits)
Sawan et al. (3) [56,59,57]	1996	8 electrodes	5 electrodes: 5 monopolar or 3 bipolar channels	no	no	no	no	6
Smith et al. [64]	1998	32 stimulation/sensor-fb channels, 8 sensor telemetry channels, 8 processed-MES telemetry channels, 8 unprocessed-MES telemetry channels, 8 system telemetry channels	9 motor-stimulation channels & 1 sensor feedback channel, 1 data-acquisition channel (Hall-effect sensors)	no	no	adjustable	12	-
Clements et al. [12,13]	1999	10 × 10 electrode array (20 channels)	10 × 10 electrode array (20 channels)	no	no	no	no	4
Park J. et al. [51]	1994	8 channels	8 channels: 7 measurement channels (2 pressure, 1 pH, 1 biopotential, 2 EEG/EMG/EKG, 1 temperature), 1 reference channel	no	no	1000	no	no
Pramassing et al. [53]	2000	32 × 32 LED display	32 × 32 LED display	no	no	no	no	no
Lande et al. [36]	2000	10 electrodes	10 electrodes driven by 10 channels each	no	no	no	no	no
Atanasov et al. [5,4,9]	1997	1 sensor	1 3-electrode glucose sensor	-	-	no	no	no
Kettlewell et al. [35]	1997	3 channels: 2 sensors (temperature, respiratory-movement), 2 electrodes: ECG	1 sensor: temperature (thermistor), 2 electrodes: ECG channel	no	no	-	no	no
Beach et al. (2) [6,7]	1999	1 sensor	1 2-electrode glucose sensor	no	no	no	no	no
Wei et al. [70]	1995	8 channels	8 channels	no	no	no	no	5
Parramon et al. [52]	1997	2 channels (2 electrode pairs)	2 channels (2 electrode pairs for EMG)	no	no	-	8	no
McCreesh et al. [40,39]	1994	1 sensor	1 sensor: temperature (thermistor)	no	no	no	no	no
Valdastri et al. [69]	2004	3 channels (3 sensors with appropriate conditioning circuits)	1 sensor (gastric pressure)	yes	yes	25 to 50 (max: 25 KHz)	10	no
Fernald et al. [21,16,22]	1991	large number of sensory/actuating peripherals	8 channels (biopotential-signal recording)	SW functions + vector operations for biomedical DSP purposes (e.g. band limiting, data compression, event detection, FIR)	yes	-	10 (peripheral-specific)	no
Harrigal et al. [31]	1990	(blood temperature, ECG)	(blood temperature, ECG)	SW functions	yes	-	-	-
D'Lima et al. [17,66,68,67]	2005	3 channels (strain gauge)	3 channels (strain gauge)	no	yes	220 divided by the no. of active channels	10	-
Park H.J. et al. [49,50,37]	2003	1 sensor	1 sensor: video (CCD camera)	no	no	128000	no	no
Harrigal et al. (2) [32]	1992	2 channels (1 sensing, 1 stimulating)	2 channels (1 sensing, 1 stimulating)	-	-	-	-	-
Von Arx et al. [3]	1999	8 channels	8 channels (stimulation)	no	no	no	no	5
Haddad et al. [27,28]	2003	5 channels	5 channels: cardiac-signal characterization	no	no	no	no	no

Table 3.8: General implant features (continued).

in device power or other constraint.

Contrary to *internal processing*, researchers are less reluctant to incorporate data memory blocks inside their implants. According to the *internal storage* field, 8 out of 41 devices (20%) feature some kind of memory, most often an SRAM, either as a discrete chip or integrated in the PCC chip. As expected, the 3 cases of devices - discussed above - that perform extra processing tasks, also include a memory block. Even though the power and chip(set)-area issues again arise when considering adding memory to an implant, the latest achievements in high-density, low-power memories (see ITRS roadmap [24]) diminish their significance.

Most biologically-generated, electrical signals have a low frequency. They display a maximum bandwidth of 1000 Hz and, thus, require a minimum sampling frequency of

2000 Hz (according to the Nyquist theorem). But a large part of them displays far narrower bandwidths, e.g. the Lundberg waves (A, B, C, D and E) in the brain manifest around the frequency of 0.09 Hz. This is verified by the numbers included in the *sampling rate* column in which rates up to 2000 Hz are commonly encountered. There are some exceptions where rates of a few kHz or even MHz are employed by the implant developers presumably for synthesizing higher-quality signals. In many cases, switching control between lower and higher sampling rates is also provided, depending on whether information needs to be recorded more or less precisely over a period of time. Finally, there are cases in which no sampling is taking place for the recorded data but rather they are transmitted directly to the outside of the body by modulating the carrier signal.

Lastly, ADC or DAC components are common circuits to be found in an implantable device and, thus, belong to this category. In case an implant contains a PCC, these components are usually built or chosen to display a resolution equal to the data-word size of the PCC, since the ADC output (DAC input) is typically fed to (supplied by) the PCC. Encountered resolutions for the ADCs are 8, 9, 10 and 12 bits while for the DACs are 3, 4 and 5 bits. These "unconventional" bit lengths give a hint about the largely customized design of implants and their PCCs which support various precision ranges depending on the medical application at hand.

3.4.5 Processing/controlling-core features

As the PCCs of the implants are of special interest in this study, the special category *PROCESSING/CONTROLLING-CORE FEATURES* has been created. Its contents are presented in the two tables 3.9 and 3.10. The *PCC architecture* field readily reveals the percentage of the studied implants that include some kind of centralized processing or control; this is equal to 28 out of 41 or, equivalently, 68%. Of the remaining 32%, some cases include implants which need to be extremely miniature in size and are designed for a very specific task, e.g. ICP measurement with the implant placed in the space between the cranium and the brain. Other study cases are not involved with the development of the whole implant but, rather, some of its parts (e.g. Min et al. [43]), thus, not concerned with a PCC in their study. Going back to the (PCC-enabled) 68% of the studied cases, 14 out of 28 implants (50%) utilize FSMs as cores (Fig.3.5). This fact alone further enforces the argument that implants are highly dedicated designs. Custom or commercial mC/mP designs are used by 8 of the 28 implants (29%) and the remaining 21% is shared among PCCs of analog nature (neural networks, spike-based processing units).

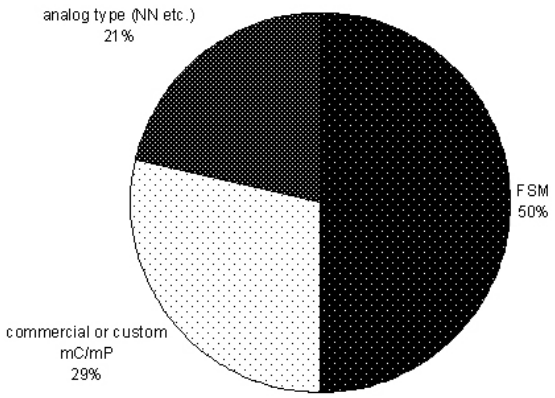

Figure 3.5: Distribution of implant architecture types.

System	Publi-cation Year	Processing/controlling-core features					
		PCC architecture	PCC frequency (MHz)	non-PCC timing (kHz)	number of instructions	instruction-word size (bits)	data-word size (bits)
Mouine et al. [44]	2000	FSM	-	-	10 (16)	3+4+9	no
Enokawa et al. [19]	1997	8-bit RISC mC	8	no	-	8	8
Flick et al. [23]	2000	no	no	no	no	no	no
Eggers et al. [18]	2000	no	no	125	no	no	no
Min et al. [43,43]	2001	no	no	4000	no	no	no
Sears et al. [61]	1999	8-bit RISC mC	-	no	-	8	8
Beach et al. [8]	2001	no	no	no	no	no	no
Huang et al. [33]	1998	no	no	100	no	no	no
Kawahito et al. [34]	1994	FSM	4	no	1	-	no
Rorie et al. [55]	1996	FSM	-	-	15	16	-
Coggins et al. [14,15]	1995	Perceptron NN	no	0.25	no	no	no
Wouters et al. [71]	1994	FSM (SIC) / 8-bit mP	0.000085 (SIC) 45 (mP)	no	16 (SIC)	-	-
Shawkey et al. [62]	1998	Kohonen NN	no	no	no	no	no
Nardin et al. [47]	1995	FSM	2	no	-	-	-
Harpster et al. [30]	2000	no	no	no	no	no	no
Lerch et al. [38]	1995	8-bit RISC mC	0.128	128	-	8	8
Akin et al. [1,2]	1994	FSM	1	no	2	start+1+(10)	no
Rollins et al. [54]	2000	FSM (PLD)	2	no	no	no	no
Shults et al. [63]	1994	no	no	no	no	no	no
Sawan et al. [60]	1996	FSM (FPGA)	0.3	no	-	8	-
Sawan et al. (2) [58]	1989	FSM & timer	-	-	4	3+8+2	8

Table 3.9: Processing/controlling-core features.

Basic clock frequencies for the PCCs, commonly range from a few MHz to 30 MHz (with a rough average at 2.5 MHz). If a PCC is missing or is analog in design, then system frequencies are reported where available and generally appear to be 3 to 4 orders of magnitude lower than for their digital counterparts, i.e. approximately in the range from 100 Hz to 1 kHz. In both cases, provided frequencies are sufficiently large to support the required sampling rates (up to 1 KHz, as previously discussed). Nonetheless, it becomes obvious that digital PCCs handle higher operating frequencies than analog ones, which are more prone to noise, drifting and other phenomena in the MHz range.

Also for the digital PCCs, columns are included in the tables for noting the supported

System	Publi-cation Year	Processing/controlling-core features					
		PCC architecture	PCC frequency (MHz)	non-PCC timing (kHz)	number of instructions	instruction-word size (bits)	data-word size (bits)
Sawan et al. (3) [56,59,57]	1996	FSM (FPGA)	1	no	-	3+21	21
Smith et al. [64]	1998	FSM	1	no	5	11	12
Clements et al. [12,13]	1999	FSM (80-bit ring timer)	1 to 10	no	no	-	no
Park J. et al. [51]	1994	no	no	no	no	no	no
Pramassing et al. [53]	2000	DSP	-	no	-	-	-
Lande et al. [36]	2000	spike-based processing	no	-	no	no	no
Atanasov et al. [5,4,9]	1997	no	no	-	no	no	no
Kettlewell et al. [35]	1997	no	no	-	no	no	no
Beach et al. (2) [6,7]	1999	no	no	-	no	no	no
Wei et al. [70]	1995	FSM mP	20	-	5 (8)	3+12	no
Parramon et al. [52]	1997	FSM	30	no	no	8	8
McCreesh et al. [40,39]	1994	no	no	no	no	no	no
Valdastri et al. [69]	2004	8-bit mC	4	no	-	8	8
Fernald et al. [21,16,22]	1991	16-bit mP	10	no	39	16	16
Harrigal et al. [31]	1990	8-bit mP	-	no	-	8	8
D'Lima et al. [17,66,68,67]	2005	8-bit mC	-	no	-	8	8
Park H.J. et al. [49,50,37]	2003	FSM (CPLD)	4	no	no	5+4	no
Harrigal et al. (2) [32]	1992	-	-	-	-	-	-
Von Arx et al. [3]	1999	16-state FSM	0.5	-	no	40+5 +2 sync pulses	40
Haddad et al. [27,28]	2003	no	no	-	no	no	no

Table 3.10: Processing/controlling-core features (continued).

number of instructions as well as instruction-word and data-word sizes. Reported instruction sets may consist of 1, 2, 4, 5, 10, 12, 15 or 16 different instructions, with the average balancing around 7. One distinct exception occurs with 39 different instructions. This is the case of Fernald et al. [21] whereby a full-blown mP for biomedical applications is proposed with its own Instruction-Set Architecture (ISA) that will be discussed later. Apart from that, all other implementations support a rather small instruction set. It is because of the dedicated design of the implants that instruction-word and data-word sizes also vary from case to case. In our study they have been found to vary between 8 *bits* and 16 *bits* with two exceptions of 21 *bits* and 40 *bits* for the data words. In these cases, the instruction words are a few bits longer due to extra control bits such as parity and other.

System	Publi-cation Year	Miscellaneous implant features					
		adjustability	multiple-peripheral support	programmability	modularity	HW/SW error handling	EMI-resistance
Mouine et al. [44]	2000	stimuli parameters	no	no	no	-	-
Enokawa et al. [19]	1997	amplifier gain	no	no	no	-	-
Flick et al. [23]	2000	no	no	no	no	-	-
Eggers et al. [18]	2000	no	no	no	no	-	-
Min et al. [43,43]	2001	no	no	no	no	-	-
Sears et al. [61]	1999	yes (unspecified)	no	no	no	-	-
Beach et al. [8]	2001	no	no	no	no	-	-
Huang et al. [33]	1998	no	sensors	no	no	-	-
Kawahito et al. [34]	1994	no	no	no	no	-	telemetry system (optical)
Rorie et al. [55]	1996	sample rates	sensors	no	no	-	-
Coggins et al. [14,15]	1995	NN training to patterns (offline)	no	no	no	NN fault tolerance	-
Wouters et al. [71]	1994	measurement parameters	no	yes	no	-	-
Shawkey et al. [62]	1998	NN training to patterns (offline)	no	no	no	NN fault tolerance	-
Nardin et al. [47]	1995	stimuli parameters	no	no	no	-	-
Harpster et al. [30]	2000	no	no	no	no	-	-
Lerch et al. [38]	1995	channel amplification/filtering, sensor current sources	data acquisition (unspecified)	yes	no	self-tests / diagnostics (CRC), scan-based testing, HW-breakpoint debugging, SW techniques, watchdogs times	-
Akin et al. [1,2]	1994	no	no	no	no	-	-
Rollins et al. [54]	2000	no	no	no	no	-	-
Shults et al. [63]	1994	transmission period/interval	no	no	no	-	-
Sawan et al. [60]	1996	stimuli parameters	no	no	no	-	-
Sawan et al. (2) [58]	1989	stimuli parameters	no	no	no	-	-

Table 3.11: Miscellaneous features.

3.4.6 Miscellaneous features

Having discussed general implant characteristics and the specifics of PCCs, some additional implant capabilities are also worth mentioning. They are included in the category *MISCELLANEOUS IMPLANT FEATURES* which is presented again in two tables, 3.11 and 3.12. The first parameter to comment on is *adjustability*. The corresponding column holds information about various user settings that the studied implantable systems provide by design. In effect, this attribute hints about the flexibility of the proposed systems: the more settings the user (patient, physician, technician) has access to, the more versatile the system. From the gathered data, 27 out of 41 implants have been found to offer some kind of user adjustment. This makes up for 66% of all cases. Usually these are second- or third-generation systems which

have augmented first-generation versions with dynamic settings, instead of static, preset ones. One common set of adjustable settings can be found, as expected, in implants that deliver electrical stimuli to e.g. paralyzed muscles or nerves. The characteristics of the stimulation pulses that are administered to a living tissue can greatly affect - positively or negatively - the therapy. Additionally, every individual requires similar but not exactly the same stimulation patterns, making therapy largely patient-dependent. Therefore, it is imperative to pinpoint this set of adjustments that best fit the patient needs per case. Typical parameters of an applied bipolar stimulation train are the two amplitudes, the high-level and low-level time, the time interval between pulses and other. Most current implementations of stimulating implants allow for this kind of adjustments. The same situation more or less exists for measurement-performing implants, too. Dynamic input range of sensory elements, adjustable data sampling rate, channel gain and bandwidth, channel amplification and filtering and ADC resolution are some of the possible settings. Also, the number of monitored channels and the transmission intervals for telemetered data are, at times, selectable.

Conclusively, researchers have gradually identified the need to build adjustable devices and have, thus, incorporated various features to support it. Apart from added patient customization and comfort, equally importantly, dynamic in-system adjustment of functional parameters gives in-vivo medical studies a great boost by allowing researchers and physicians to easily test various parameter combinations (e.g. stimulation trains) in test subjects without the need for repeated implantation and explantation surgeries which are tedious, unpleasant and often dangerous ordeals. For these reasons, in future systems, the adjustability issue inarguably needs to be not simply maintained but further improved with more features of wider ranges.

A small percentage of the studied implants (about 10%) goes a bit further and features designs that accept a limited gamut of interchangeable peripherals. More specifically, these devices support a number of different sensor (or other) chips by providing channels with adjustable characteristics, much like the ones described above. They can, therefore, configure their readout electronics to the sensitivity, speed and, less commonly, the resolution of the ported sensors. Of course, limitations exist in this approach since the *multi-peripheral support* feature depends on the powering scheme (interface, consumption) of a plugged-in peripheral and also on its output type. For example, if a sensor outputs PWM-modulated data but the implant "understands" only PCM signals, direct interfacing between the two is not possible unless extra glue-circuitry is included. It is stressed here that the column *multi-peripheral support* refers to interchangeable support of (pluggable) peripherals and not to simultaneous support of (a number of statically connected) peripherals, as discussed in the category *GENERAL IMPLANT FEATURES* (I/O columns).

The *programmability* field includes all those devices that realize their functionality by executing source code from a program memory, i.e. their control is software-based and not hardwired or hard-coded. This is an interesting-to-know feature since it reveals implantable systems that can adapt their functionality to more than one application by

System	Publi-cation Year	Miscellaneous implant features					
		adjustability	multiple-peripheral support	programmability	modularity	HW/SW error handling	EMI-resistance
Sawan et al. (3) [56,59,57]	1996	stimuli parameters	no	no	no	-	-
Smith et al. [64]	1998	stimuli parameters, sensor sample rate / powering parameters, data-acquisition electrode sample rate, internal-system-function channel parameters	yes	no	no	system-control circuitry for interrogation and configuration of implant in case of error	-
Clements et al. [12,13]	1999	stimuli parameters	no	no	no	-	-
Park J. et al. [51]	1994	no	no	no	no	-	-
Pramassing et al. [53]	2000	no	no	no	no	-	-
Lande et al. [36]	2000	channel gain, channel frequency-band mapping	no	no	no	insensitivity to stuck-at faults (spike-based processing), redundancy by encoding similar information in neighboring channels	-
Atanasov et al. [5,4,9]	1997	transmission period/interval	no	no	no	-	-
Kettlewell et al. [35]	1997	no	no	no	no	-	-
Beach et al. (2) [6,7]	1999	transmission period/interval	no	no	no	-	-
Wei et al. [70]	1995	stimuli parameters	no	no	no	-	-
Parramon et al. [52]	1997	number of monitored channels	no	no	no	-	-
McCreesh et al. [40,39]	1994	no	no	no	no	-	-
Valdastri et al. [69]	2004	number of monitored channels, sample rates etc.	yes	in-circuit mC reprogramming	no	-	-
Fernald et al. [21,16,22]	1991	channel gain/bandwidth (peripheral-specific), adjustable parameters of peripheral modules and SW-controlled functions	yes	in-circuit mC reprogramming	yes	-	-
Harrigal et al. [31]	1990	ADC resolution, SW-controlled functions	no	yes	no	watchdog (continuous, high-reliability testing and backup circuit)	-
D'Lima et al. [17,66,68,67]	2005	SW-programmable channel-gain / filter-range, sample-rate	various types (DC, AC) of pressure sensors	no	no	-	PCM for telemetry instead of PWM (PCM more robust against EMI)
Park H.J. et al. [49,50,37]	2003	selective powering of camera/LEDs	no	no	no	-	-
Harrigal et al. (2) [32]	1992	stimuli parameters	no	-	no	-	-
Von Arx et al. [3]	1999	stimuli parameters	no	no	no	-	-
Haddad et al. [27,28]	2003	no	no	no	no	no	-

Table 3.12: Miscellaneous features (continued).

reprogramming their control and processing behavior (and by plugging in the proper peripherals). Such systems are also expected to feature internal-storage properties since they require program memory but also data memory to execute their programs. From the corresponding tables this is confirmed by 5 out of 8 memory-including systems possessing software (re)programming capabilities. Additionally, such systems

should also have *multiple-peripheral support* (as previously discussed); in order, to serve different applications they should modify not only their software but also their peripherals. The tables reveal this to be partly true, with 3 of the above 5 implants complying. The 2 remaining implants, even though featuring a programmable core, have been tightly sawn for the specific design, with statically defined, application-specific instructions, no interchangeable peripherals etc.. Last, it is worth mentioning that two of the programmable systems support in-circuit PCC reprogramming, i.e. program-code downloading through the wireless interface with the host.

Having discussed *multiple-peripheral support* and *programmability* traits of implants, it makes sense to query the studied cases for those devices that are modular in design, i.e. devices that have been designed generically enough so that their core can be reused in very diverse applications. By "reusability" we don't simply imply those devices that can support a specific set of different peripherals - this is the above seen *multiple-peripheral support*. Instead, we consider implants which are based on an architecture capable of supporting a (theoretically) infinite number of application setups, i.e. a general-purpose core which can be used in various biomedical scenarios with no modifications whatsoever. Only one of the studied implants has been consciously based on a generic (as opposed to highly dedicated) design for the PCC part, introduced by Fernald et al. [21]. If system-wide (as opposed to PCC-only) architecture be considered, then none of the studied implants features generic, reusable design.

While this design approach sanctioning IP reusability is tested and proven in other, non-biomedical fields, our study on the past and present state of art reveals that, until now, it has not truly been adopted in microelectronic-implant design. However, we consider this to be an excellent design recipe and well-suited for this field, too. It can potentially offer a tremendous boost to implantable systems by allowing researchers to develop, exchange and utilize IP cores which are guaranteed to work and are already proven in some other implant design. Such reusable and modular designs will shorten development times and will minimize testing and verification costs - which are non-trivial altogether - and especially in the biomedical domain where (inter)national regulations are most stringent. Few generic implant designs have been proposed over the last 15 years or so and, while their significance is not larger now than it was then, recent advances in CMOS microtechnology make generic design more plausible now and allow for new approaches to the subject, previously considered as unrealistic.

In the same train of thought, it is noted that none of the studied devices features any kind of dynamic hardware reconfigurability. Even though quite some implants have been realized as structured designs (e.g. FPGAs, CPLDs), not a single one of them provides for some kind of in-circuit reconfigurability of (part of) their logic cells. Such reconfigurable logic cells could be adjusted, per case, to perform specific demanding operations in hardware, lifting the processing burden from the PCC or from any peripheral circuitry. On selecting other intensive tasks, the logic cells could be reconfigured to pick those tasks. Given the advances made in field-programmable chips over the last years, the inclusion of a small area with reconfigurable cells is envisioned

to bear great benefits for the average power consumption of an implant. Obviously, the optimum amount of logic cells to include in an implantable system (at the cost of area for logic cells and interface to the rest of the system) is a non-trivial problem which depends on various design parameters and needs further elaboration.

Under the column termed *HW/SW error handling*, reported are various techniques employed by the implants for detecting and even correcting errors occurring during operation. This is a crucial feature of implantable systems given the delicate nature of the biomedical field, yet, only few of them appear to be actively involved in the matter. To be exact, only 3 out of 41 cases take measures against errors. Namely, one resorts, at startup, to self-tests and CRC-based diagnostics while, at operation time, in hardware break-point debugging for its executed source code and other software-based techniques (not specified). The specific implementation even features fabrication-time scan-based testing to verify the error-free implementation of the implant electronics. The second of the three implants vaguely supports "system-control circuitry for interrogation and configuration of implant in case of error" while the third one (implementing a pacemaker) features "continuous, high-reliability testing and backup circuitry". If to the above 3 cases we also include two neural-network implementations (Coggins et al. [14], Shawkey et al. [62]) which are intrinsically fault tolerant and one (analog) spike-based processing system (Lande et al. [36]) which intrinsically provides insensitivity to stuck-at faults and redundancy by similar information encoding, a total of 6 out of 41 implants (15%) is found - an unexpectedly small percentage given the context. It should be noted, however, that for the rest of the cases, no information on the error-handling issue is provided by the authors, as can be seen from the corresponding tables. This means that more cases of error-handling might be included but simply not reported, effectively increasing the above percentage of 15%. Nonetheless, it is our strong belief that error handling is a non-trivial feature of implantable systems and, as such, should be explicitly reported by every researcher. On these grounds, we stand by our initial percentage estimation.

In the category *MISCELLANEOUS IMPLANT FEATURES* a final column has been included for reporting all those implantable systems that are actively designed to minimize the effects of EMI on their normal function. The results show only 2 out of 41 researchers to be discussing the issue. Both of them are concerned only with EMI-free wireless communication between the implant and the external host. One of them utilizes near-IR instead of RF links for data exchange while the other resorts to PCM-modulating of telemetered data since it is more robust against EMI than PWM modulation. Again, all other studied researchers do not mention EMI in their designs, which means that - in truth - more than 2 of them may have gotten involved with the issue, but this is considered highly unlikely. The poor involvement of researchers in this issue, especially these days that the ambient is filled with EM-noise from various sources (MRI scanners, mobiles, wireless LANs, GPS, airport metal-detector doors etc.) is very surprising.

System	Publi-cation Year	Wireless-communication features						
		multipoint-communication support	communication type	Rx-modulation scheme	Rx-carrier frequency (MHz)	command encoding scheme	command-packet size (bits)	command rate (kbps)
Mouine et al. [44]	2000	-	inwards	AM	20	Manchester	3+4+9	-
Enokawa et al. [19]	1997	-	bidirectional	OOK	0.2	-	8	0.144
Flick et al. [23]	2000	-	outwards	no	4	no	no	no
Eggers et al. [18]	2000	-	outwards	no	4	no	no	no
Min et al. [43,43]	2001	-	outwards	no	-	no	no	no
Sears et al. [61]	1999	-	bidirectional	DSSS	2450	-	-	159
Beach et al. [8]	2001	-	outwards	no	no	no	no	no
Huang et al. [33]	1998	-	outwards	no	27	no	no	no
Kawahito et al. [34]	1994	4	bidirectional	-	950 (nm)	-	-	-
Rorie et al. [55]	1996	-	bidirectional	-	-	-	16	-
Coggins et al. [14,15]	1995	no	no (inside ICD)	no	no	no	no	no
Wouters et al. [71]	1994	-	bidirectional	ASK	0.132	-	-	-
Shawkey et al. [62]	1998	no	no (inside ICD)	no	no	no	no	no
Nardin et al. [47]	1995	yes	bidirectional	AM	1.8	-	-	-
Harpster et al. [30]	2000	-	outwards	no	-	no	no	no
Lerch et al. [38]	1995	-	bidirectional	-	-	-	-	-
Akin et al. [1,2]	1994	-	bidirectional	AM	-	PWM	start+1+(10)	-
Rollins et al. [54]	2000	-	outwards (wired)	no	no	no	no	no
Shults et al. [63]	1994	40	outwards	no	no	no	no	no
Sawan et al. [60]	1996	-	inwards	AM	20	Manchester	8 (+8+8+...)	300
Sawan et al. (2) [58]	1989	-	inwards	-	-	Manchester	3+8+2	-

Table 3.13: Communication features.

3.4.7 Communication features

The last category to be investigated is concerned with the specifics of the wireless communication interface present in the majority of implantable systems. Due to excessive size, four tables have been produced, namely 3.13, 3.14, 3.15 and 3.16. The first reported parameter, *multipoint-communication support*, refers to the maximal number of implants of the same type that can be collocated in the same application area, for instance inside the body of the same subject. Plausible scenarios for such a capability can be: a) a set of single-channel implantable microstimulators which are placed in different sites inside a patient's body and each wirelessly receives its own stimulation commands for execution, and b) a hospital setup where patients in the same post-operation, recovery room have each an implantable ECG-monitoring device which - simultaneously to the others - telemetries ECG data to an external desktop computer

where a physician monitors their status. In this study, 9 out of 41 such designs have been encountered, featuring ranges from 4 up to 40 identical devices to coexist in proximity to each other. This ability to coexist is implemented through various communication schemes, e.g. i) a frequency-division scheme for receiving/transferring data is used, ii) a strict time-division scheme over a single frequency is used, or iii) ID-based data transfer with devices distinguishing which packets are meant for them (by matching IDs) is used. In the last case, ID matching is usually performed by the PCC of the implant which compares received IDs with internal unique hardwired or software-programmed ID codes.

From the tables it is confirmed that the majority of developed implants (at least microelectronic ones), features some kind of wireless communication with the outside of the body. More specifically, 13 of 39 implants (33%) telemeter data externally, 8 of 39 implants (21%) receive and execute commands from an external host and 14 of 39 implants (36%) perform both operations, for a total of 90% (Fig.3.6). The remaining 6 cases (10%) either feature no (or wired) communication or give no relevant information.

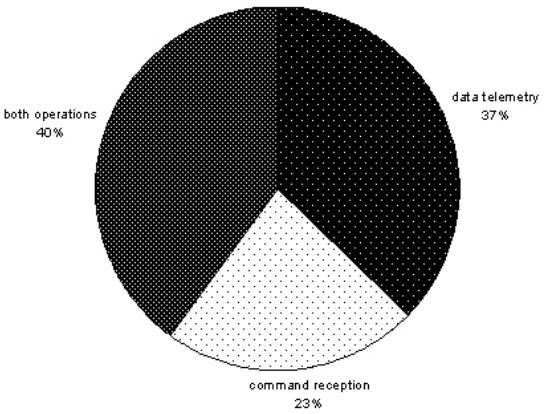

Figure 3.6: Distribution of implant wireless-communication types.

Various modulation and information-encoding techniques have been encountered in this study, both for incoming and outgoing communication. As far as modulation techniques are concerned, commonly selected for incoming commands are amplitude-modulation techniques (AM, ASK, OOK) whereas for outgoing data are amplitude-modulation techniques (AM, ASK), frequency-modulation techniques (FM, FSK), phase-modulation techniques (PSK, BPSK) and also the technique known as impedance-reflection modulation. Since (information) signal modulation and demodulation inside the implant has to be as simple and power efficient as possible, many of the above techniques have been picked due to their implementation simplicity or low power requirements. Impedance reflection [6] can be used only in cases where back-telemetry from the implant is required (over an existing incoming RF link). This is a passive transmission technique which removes the need for an active transmitter circuit in the implant. The implant simply "reflects" its load (in its receiver) to the circuit of the external transmitter over the inductive link formed (and powered) solely by the external transmitter. This scheme dramatically reduces power consumption in the telemetry peripheral of the implant, yet one should not forget that it cannot support complex data-transfer schemes (e.g. data multiplexing) or high data transfer rates - typical rates are equal to 200 $kbits/sec$. Nonetheless, such a performance is more than adequate for satisfying the needs of a large set of biomedical applications, namely in our study 35% or more of those implants supporting back-telemetry.

System	Publi-cation Year	Wireless-communication features						
		multipoint-communication support	communication type	Rx-modulation scheme	Rx-carrier frequency (MHz)	command encoding scheme	command-packet size (bits)	command rate (kbps)
Sawan et al. (3) [56,59,57]	1996	-	inwards	AM	20	Manchester	3+21	300
Smith et al. [64]	1998	4	bidirectional	OOK	6.78	-	1+1+11	-
Clements et al. [12,13]	1999	-	inwards	ASK	1 to 10	PWM (alternate mark inversion)	-	30 to >1000
Park J. et al. [51]	1994	8	bidirectional	missing pulse	-	-	no	no
Pramassing et al. [53]	2000	-	inwards	-	absorption-minimum of blurred cornea	Manchester	-	1000
Lande et al. [36]	2000	-	-	-	-	-	-	-
Atanasov et al. [5,4,9]	1997	-	outwards	no	no	no	no	no
Kettlewell et al. [35]	1997	-	outwards	no	no	no	no	no
Beach et al. (2) [6,7]	1999	40	outwards	no	no	no	no	no
Wei et al. [70]	1995	-	inwards	AM	20	Manchester	3+12	-
Parramon et al. [52]	1997	-	bidirectional	ASK	10	RZ	8	-
McCreesh et al. [40,39]	1994	-	outwards	no	no	no	no	no
Valdastri et al. [69]	2004	yes	outwards	no	no	no	no	no
Fernald et al. [21,16,22]	1991	-	bidirectional	-	40	PWM	1+16+(1024) +16+(16)	-
Harrigal et al. [31]	1990	-	-	-	-	-	-	-
D'Lima et al. [17,66,68,67]	2005	-	outwards	-	0.0016	-	-	-
Park H.J. et al. [49,50,37]	2003	32	bidirectional	OOK	433	-	5+4	-
Harrigal et al. (2) [32]	1992	-	bidirectional	-	-	-	-	-
Von Arx et al. [3]	1999	yes	inwards	AM	4	PWM	40+5 +2 sync pulses	8.300
Haddad et al. [27,28]	2003	no	no (inside pacemaker)	no	no	no	no	no

Table 3.14: Communication features (continued).

Utilized carrier frequencies for the various modulation techniques present, for incoming links, a large dispersion with values as low as 1.6 kHz and as high as 2.45 GHz (ISM band). For outgoing links, values as low as 66 kHz and as high as 1.2 GHz have been encountered in this study. From these figures it can be extracted that implant transmitters in general use carriers of lower frequency (marginal and average) that that of external-host transmitters. This is somewhat expected since implants cannot

[6]In a nutshell, impedance reflection modulation is achieved by altering the value of the impedance in the secondary coil of the link (i.e. on the receiving coil of the implant) according to some measured physiological parameter. Then, by basic electronic circuit theory, the implant impedance (i.e. load) is "reflected" in the transmitter antenna circuit (due to the established mutual induction). A change of the impedance in the (external) antenna circuit shall result in a change in the antenna current which is easily measured. For more information on the subject refer, for instance, to [29].

System	Publi-cation Year	Wireless-communication features (continued)					
		Tx-modulation scheme	Tx-carrier frequency (MHz)	data encoding scheme	data-packet size (bits)	data rate (kbps)	communication error handling
Mouine et al. [44]	2000	no	no	no	no	no	-
Enokawa et al. [19]	1997	impedance reflection	no	-	13+8+sync	-	no
Flick et al. [23]	2000	impedance reflection	no	PWM	-	-	no
Eggers et al. [18]	2000	impedance reflection	no	PWM	-	-	no
Min et al. [43,43]	2001	-	-	-	-	-	-
Sears et al. [61]	1999	DPSK	no	-	8+5	92	5 error-correction codes etc. (MicroStamp Engine)
Beach et al. [8]	2001	standard TV-signal	433.25 (UHF)	EIA / NTSC	no	no	no
Huang et al. [33]	1998	impedance reflection	no	no	9+sync	0.1	no
Kawahito et al. [34]	1994	pulse-interval	850 (nm)	-	-	-	no
Rorie et al. [55]	1996	-	-	-	-	-	retransmission w/ complementation, status-word back transmission on error
Coggins et al. [14,15]	1995	no	no	no	no	no	no
Wouters et al. [71]	1994	ASK / PSK	0.066	-	varies w/ cmd	-	-
Shawkey et al. [62]	1998	no	no	no	no	no	-
Nardin et al. [47]	1995	AM	33	-	-	-	stop-and-wait scheme (verify cmd back), parity bit
Harpster et al. [30]	2000	impedance reflection	no	no	no	no	no
Lerch et al. [38]	1995	FSK	-	-	-	-	-
Akin et al. [1,2]	1994	transmitter/receiver-coil induction	no	PWM	16	-	reception time outs
Rollins et al. [54]	2000	no	no	no	16	144	no
Shults et al. [63]	1994	AM and FM	86 to 87.95	sine wave (300 to 500 Hz)	no	no	no
Sawan et al. [60]	1996	no	no	no	no	no	header detection
Sawan et al. (2) [58]	1989	no	no	no	no	no	bit error correction

Table 3.15: Communication features (continued).

compete with external communication blocks due to power and size considerations, as usual. In many cases, the exact carrier frequency is also determined by biomedical factors, i.e. for achieving minimal absorption and power dissipation in the tissue that exists between the implant and the external host. This heavily depends on the tissue type and, therefore, in the site of the body that the implant is designed to be placed.

For instance, a telemetric temperature probe placed inside the vagina (McCreesh et al. [40]) has been specifically set to transmit at 424 MHz whereas a gastric-pressure measuring implant (Valdastri et al. [69] has been set to transmit at 433.92 MHz.

Considering data-encoding schemes adopted by the studied implants, popular ones for incoming commands have been Manchester coding and PWM coding (various flavors). Both allow transmitted command trains to also carry (external) clock-signal information to the implant inherently which is then used for synchronization purposes or even for providing the implant with a clock signal (i.e. no internal clock generator is implemented). For outgoing data, the most common technique used is again PWM coding. There are, though, some cases where digitization (and, thus, encoding) of physiological data does not take place, e.g. in the implantable CCD camera of Beach et al. [8], whereby the sensor outputs directly NTSC-compatible signals which are directly transmitted (in analog fashion) over a UHF frequency to an external host.

Similar to the instruction- and data-word sizes inside the PCCs, command- and data-packet sizes in the wireless communication protocols also vary largely. Command packets of 8, 9, 11, 13, 14, 16, 24, 47 and more bits have been reported with an average size somewhere between 8 *bits* and 16 *bits*. In the same manner, data packets of 4, 8, 16, 22 and more bits exist with an average size larger than that of the command packets. A great difference over the instruction and data words discussed in the category *PROCESSING/CONTROLLING-CORE FEATURES* is that communication packets can vary significantly in size depending on the type of information or the purpose they are serving at the time. Of course, this is very common in communication protocols. As a rather excessive example of the variety of sizes, the implantable system proposed by Fernald et al. may during communication handle a packet of 33 *bits* or a packet of 1073 *bits*. Lastly, it is stressed out again that communication packets are not necessarily the same data as the words that are fed in a PCC. In some cases (especially of simplistic FSM-type PCCs), the command packets are the actual instruction words that are received by an implant and fed to its PCC for error checks, decoding and execution. In other cases, over-the-air commands are received by the telemetry module, decoded and broken down to the actual commands that are only then fed to the PCC.

As far as the maximally supported command and data rates are concerned, researchers fail to report them in many cases. Dispersion of available values is again present, even though commands are, once more, leading with performances reaching (and at times surpassing) 300 *kbps* over data with best rates typically ranging from 150 *kbps* to 200 *kbps*. The reason for this difference is the same as above, for carrier frequencies. Implants are more conservative in delivering higher performance for upper-bounding mainly power but also size requirements. Nevertheless, there are a few cases in which implants are designed to receive (Clements et al. [12]) or telemeter (Park H.J. et al. [49]) digital images at actual visual rates. In such cases, command and data rates are as high as 1000 *kbps* and 2000 *kbps*, respectively.

To complete the elaboration on the communication part of implantable devices,

System	Publi-cation Year	Wireless-communication features (continued)					
		Tx-modulation scheme	Tx-carrier frequency (MHz)	data encoding scheme	data-packet size (bits)	data rate (kbps)	communication error handling
Sawan et al. (3) [56,59,57]	1996	no	no	no	no	no	-
Smith et al. [64]	1998	impedance reflection	no	-	12+2	-	1 parity bit, handshaking
Clements et al. [12,13]	1999	no	no	no	no	no	-
Park J. et al. [51]	1994	FSK	80	PWM	no	no	no
Pramassing et al. [53]	2000	no	no	no	no	no	-
Lande et al. [36]	2000	-	-	-	-	-	-
Atanasov et al. [5,4,9]	1997	FM	88 to 108	square wave (varying freq.)	no	no	no
Kettlewell et al. [35]	1997	FM	173.20 to 173.35	no	no	no	no
Beach et al. (2) [6,7]	1999	OOK	303.825	-	-	-	-
Wei et al. [70]	1995	no	no	no	no	no	-
Parramon et al. [52]	1997	BPSK	30	-	8 +(8 sync)	468 or 234	command retransmission, echo frame
McCreesh et al. [40,39]	1994	PAM	418 (UHF)		no	no	no
Valdastri et al. [69]	2004	ASK	433.92	EIA232C	1+1+2+2+16	40 (13 per channel)	error detection (parity bit)
Fernald et al. [21,16,22]	1991	PSK	40	-	1+16+(1024)+ 16+(16)	100 (avg)	cmd/data-checksum with complementation
Harrigal et al. [31]	1990	-	-	-	-	-	-
D'Lima et al. [17,66,68,67]	2005	-	916	PCM	-	4.8	-
Park H.J. et al. [49,50,37]	2003	FSK	1200	-	8+horiz / vert / pixel-sync	2000	-
Harrigal et al. (2) [32]	1992	-	-	-	-	-	-
Von Arx et al. [3]	1999	no	no	no	no	no	5 error detection bits, cancel stimulation on error
Haddad et al. [27,28]	2003	no	no	no	no	no	no

Table 3.16: Communication features (continued).

a last column is included which (similarly to the PCC-related part) contains all error-handling schemes included in the examined systems. Some of them implement full-blown communication protocols featuring handshaking, command retransmission (with complementation) on time-out or on negative acknowledgement (NAK), reception acknowledgement by packet echoing. Additionally, many implants have utilized various error detection and error correction schemes by including parity bits and error-correcting codes (such as CRC checksums) in the wirelessly transmitted information packets. The percentage of devices featuring error-handling communication is 44%, i.e. 11 out of 25 implants (the remaining 15 did not provide relevant information). As in the case

of *HW/SW error handling*, robust communication is considered to be a crucial issue towards the very safety of the patient. Based on measured physiological data, physicians are often called to make serious medical choices that will drastically affect the health of their patients. Moreover, implants that intervene in the functionality of the human body, such as microstimulators, need to guarantee safe application of their functions at all times. For such reasons, information transmission needs to be error-free at all costs.

Even though wireless communication gives flexible connectivity previously unimaginable, it also allows for unwanted interlopers to jump in in the conversation and "overhear" the private information exchanged between implant (i.e. patient) and external host (i.e. treating physician). Based on this fact, error-free implant communication will just not be enough in the years to come. In order to safeguard the privacy and personal (biological) data of its carrier, an implant shall also be required to feature information encryption over the wireless link. Of course, this issue is not phenomenal. Data security has been a concern of increasing importance for many - already mature - communication networks (e.g. internet, mobile networks etc.). Migration to the biomedical field is rather expected, nonetheless should not be treated with less severity.

3.5 Chapter summary

This chapter has presented a taxonomy of the implantable systems studied in the previous chapter. A large number of different device parameters have been included, resulting in a rather detailed classification (although some implant aspects have been consciously omitted or constrained). The data have been concentrated in tables and, based on them, a rather involved commentary of the findings has been given.

4 Conclusions

The topic of this document has been the study and classification of biomedical, implantable, microelectronic devices. We have been primarily motivated by two observations: the first one is the astounding potential such devices show for treating many common or special medical problems - previously impossible or hard to solve by the medical science (or any other science, for that matter). The second observation especially applies to the microelectronic implants (which are main concern of this work); it refers to the heady progress achieved in microelectronic technology. By allowing the design of miniature-size devices with sub-milliwatt power requirements, microelectronics have paved the way for new generations of implantable systems featuring a multitude of functions for solving a large number of medical problems.

In view of these facts, we have performed a broad and scrutinous survey of implantable systems which have been proposed by researchers and - at times - commercialized by companies over a period of almost 20 years. In what appears to be a booming field, effort has been put to include representative systems of various implementations and destined for diverse biomedical applications, so as to synthesize a comprehensive picture of the current state of the art. The survey has been set up to collect, organize, at times clarify and, finally, report information for each studied system in a carefully structured manner. Implantable systems being complex designs, their constituent parts - internal (in-vivo) components, external (ex-vivo) components, communication between the two and electromechanical characteristics (such as power consumption and physical dimensions) - have been separately discussed for each studied case.

Based on the findings of the survey, an exhaustive classification of the studied systems has been presented. Careful organization of the bulk of gathered information has been again the key element and the various implantable-system features have been grouped in categories. Most of them have been deliberately built to loosely match the above-discussed system parts. We have, then, complemented our classification with an in-depth annotation of the findings. Observations are made and general conclusions have been drawn, with the major ones being as follows:

- Stimulation of nerves/muscles and measurement of various physiological parameters are the two most commonly encountered functional roles of microelectronic implants designed so far.

- The majority of proposed implants are mixed-signal, full-custom devices. A large number of them coordinate their functionality based on a central processing and/or controlling unit (PCC), usually of dedicated design.

- Low power consumption is a primary concern of all implantable systems. The average power consumption encountered in the study is approximately equal to 165 mW while the maximum one is approximately equal to 1000 mW.

- All implants are powered either by an in-system (implantable) battery or by power transfer over a (wireless) inductive link. Most battery-powered implementations and a few externally powered ones feature some kind of low-power mode.

- Most implant implementations that include a PCC, deliberately avoid performing high-level operations on it for conserving power. The currents trends of modern microelectronic technology towards ultra low power consumption, combined with smart low-power techniques in software or hardware, can help alleviate this limitation.

- Currently, very few researchers take active interest in developing some kind of hardware- and/or software-based technique for handling (detecting, correcting) errors and faults during normal implant operation. Such techniques have a tremendous impact on device reliability (on the system level). Given the medical content of the targeted applications, the absence of such techniques from existing implementations is considered a major deficiency.

- The majority of microelectronic implants features some kind of wireless communication with the outside of the body (inwards only, outwards only, bidirectional). For the implants, mostly simple coding, modulation and demodulation techniques are employed for keeping design complexity and power consumption low.

- In this study, nearly half the study cases that support wireless communication, also feature some error-handling scheme to make information exchange more robust. All future designs ought to implement such a scheme for improving the reliability factor, especially in the modern "noisy" environment of wireless communications.

- Implant design for: i) simultaneous (in-system) multi-peripheral support, ii) interchangeable (out-of-system) multi-peripheral support, iii) adjustability of peripheral settings, and/or iv) programmability (in-system and out-of-system) has been identified and increasingly pursued by various researchers as experience and technology mature.

- A feature that is most promising for taking implant design a step further than the previous list of desired traits, is modularity, i.e. Intellectual-Property (IP)-based design for reusability. Only one researcher has proposed a generic PCC design and none of them one on a system level. Yet, as other technology fields have shown, IP-based design (as opposed to highly customized and dedicated design) will allow for fast-developed types of standardized implantable devices. Modern advances in microtechnology (featuring miniature size and ultra low power consumption) can sanction such an approach and lead to flexible, reliable and power efficient implantable systems, easily designed for different applications by IP reuse.

- No present implant implementation features any kind of dynamic hardware reconfigurability. Latest advances in the characteristics of reconfigurable circuits, also encourage investigation of such a case. Outright benefits are envisioned to be lower power requirements and higher performance for the implants by dynamically mapping processing-intensive tasks of the implant to reconfigurable hardware.

- Power dissipation of implants to the surrounding tissue is an overlooked topic (or at least, not mentioned) by most of the reported researchers. Nonetheless, it is considered a crucial issue and a primary concern for many aspects of implant design, including system-level architecture.

- EMI resistance is considered a hot topic these days with the ambient being filled with EM-noise from various sources (MRI scanners, mobiles, wireless LANs, GPS, airport metal-detector doors etc.). Even so, the involvement of most implant developers with this issue has been extremely poor and should be seriously increased in future implant designs.

- Error-free implant communication with the external environment is crucial but it is not enough, especially in the years to come. In order to safeguard the privacy and personal (biological) data of its carrier, an implant shall also be required to feature information encryption over the wireless link. Currently, explicit data security is not present in any of the studied systems.

Conclusively, the presented classification and commentary are the major contributions of this thesis since, to our knowledge, no similar attempt has been made so far on the broad field of microelectronic implants. This document gives a thorough view of the field, enables us to offer a first educated opinion on its trends and potentials and also to share directions for future work.

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Curriculum Vitae

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