



2. SYSTEM OVERVIEW

2.1 SYSTEM DESCRIPTION

The SOCR System (Figure 1) contains electronics that control the continuous stimulation and sensing required to collect real-time intracardiac impedance and heart sounds signals. The impedance signals are collected from selected electrode vector configurations using the subject's implanted pacing leads/LV catheter and an investigational impedance pacing unit, the Model 19061 Acute Human Monitor (AHM) Module. A Model 2090 programmer with the SOCR Investigational Software along with a switch on the front panel of the AHM Module allow the user to select specific electrode vector configurations for current stimulation and voltage sense measurement. The heart sounds signals are collected from an investigational Model 19062 Heart Sound Sensor Device placed on the subject.

Real-time impedance and auxiliary signals from analog output terminals of the AHM Module, real-time heart sounds and EGM/marker signals from the two programmers through a 2090A/B Analog Output Module, and real-time LV pressure signals from the Millar PCU-2000 are transmitted to the applicable Biopac Data Acquisition System's analog input terminals. The Biopac Data Acquisition System transmits the acquired analog input signals to the computer's data acquisition software [AcqKnowledge[®]] which subsequently saves the data to the computer's hard disk and displays real time waveform data on the computer's display.

The AHM Module also contains circuitry for standard pacing interventions with the implanted right atrial (RA) lead, right ventricular (RV) pacing lead, and left ventricular (LV) pacing lead or catheter. The leads are connected to an investigational Model 15420 Patient Cable in order to interface with the AHM Module. The LV catheter is directly connected.

The Biopac MP150 Data Acquisition System also collects physiologic signals from standard EP laboratory equipment used for subject monitoring during device implant. These physiologic signals may include ECG, blood pressure, or other physiologic signals. Available physiologic signals can be recorded simultaneously with the above signals but are not required by Medtronic to obtain the study objectives.

The SOCR system is shown pictorially in Figure 1.

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Table of Contents May 2013 Socr

1. Understanding the eBook May 2013 Socr
 - The Rise of Digital Reading May 2013 Socr
 - Advantages of eBooks Over Traditional Books
2. Identifying May 2013 Socr
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an May 2013 Socr
 - User-Friendly Interface
4. Exploring eBook Recommendations from May 2013 Socr
 - Personalized Recommendations
 - May 2013 Socr User Reviews and Ratings
 - May 2013 Socr and Bestseller Lists
5. Accessing May 2013 Socr Free and Paid eBooks
 - May 2013 Socr Public Domain eBooks
 - May 2013 Socr eBook Subscription Services
 - May 2013 Socr Budget-Friendly Options

6. Navigating May 2013 Socr eBook Formats
 - ePub, PDF, MOBI, and More
 - May 2013 Socr Compatibility with Devices
 - May 2013 Socr Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of May 2013 Socr
 - Highlighting and Note-Taking May 2013 Socr
 - Interactive Elements May 2013 Socr
8. Staying Engaged with May 2013 Socr
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers May 2013 Socr
9. Balancing eBooks and Physical Books May 2013 Socr
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection May 2013 Socr
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine May 2013 Socr
 - Setting Reading Goals May 2013 Socr
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of May 2013 Socr
 - Fact-Checking eBook Content of May 2013 Socr
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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