HISTORY OF ELECTROCARDIOLOGY

The History of Clinical Holter Monitoring

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Presented here is a 40-year review of Del Mar Avionics’ Medical Systems Division, highlighting the company’s clinical application teamwork with members of the International Society of Holter and Noninvasive Electrocardiology and other cardiologists worldwide to develop and apply its novel long-term clinical ambulatory heart monitoring instrumentation for reporting and managing abnormal rhythm and conduction conditions of the heart and its cardiovascular system.

Sudden death by heart attack on presumed healthy people is a very shocking experience for everyone associated with the victim. Now here was a challenge facing the medical profession in the 20th Century! They saw the need to intensify the search for early warnings of a possible heart attack! They needed to increase cooperation with the pharmaceutical industry to find some new heart-relaxing and seizure-preventing drugs. They needed to offer more support to the research in laboratories associated with hospitals. It was up to cardiologists to increase their effort and lead the way in the effort to reduce the incidence of sudden death by heart attack! This article is a testimonial to the people who developed and applied the noninvasive ambulatory long-term heart monitoring procedure that became known late in the 20th Century as Holter Monitoring, and who used its discoveries of cardiac abnormalities to effectively treat the patient and thereby meet that challenge.

In Beverly Hills, California, Cedars-Sinai Hospital and its medical staff rose to the challenge. They established there an animal research laboratory in the late 1950s to invasively explore animal cardiovascular systems and to determine the strength and weakness of a cardiovascular system under various adverse conditions. Cardiologist Dr. Eliot Corday was assigned to head that laboratory.

After only getting started with the establishment of Del Mar Engineering Laboratories in 1952, I was building a close working relationship with a 35-year-old aeronautical engineer, Joe Hopper, who had joined me from Douglas Aircraft Company as my Chief Engineer. One morning in 1954, without any warning, he was struck by a sudden heart attack. He was rushed to the hospital, and, by the end of the day, he died. This was a blow I had never anticipated, and which I can never forget! I vowed then that I would, in Joe Hopper’s memory, make a major effort to assist the medical profession by developing instrumentation that would provide the cardiologist with a “window on the heart.” Could not we be able to receive a warning and take some action to reduce the incidence of sudden human death by heart attack?

The 10-year period from 1952 to 1962 was good for Del Mar Engineering Laboratories as it kept the company busy in the development of aerial weapons training instruments for the age of jet-engine-powered aircraft of the US Military Forces and those of other Free-World nations.

In the late 1950s, after the years of interesting aerospace electromechanical product development, our company’s operations moved to Los Angeles International Airport and was open to new opportunities for a broader utilization of our assets in technical manpower and manufacturing facilities. I received a call from Dr. Eliot Corday, the research cardiologist practicing at Cedars-Sinai Hospital in Beverly Hills, California. Dr. Corday called me from his animal research laboratory about his need for some special instrumentation. I had been recommended to him as an inventor and manufacturer of electronic instrumentation. After visiting...
The History of Clinical Holter Monitoring

Dr. William Thornton, B.S. Physics ‘52 and M.D. ‘63, University of North Carolina, was medically retired after 27 years with many honors as a NASA Scientist Astronaut (and flying twice on Challenger, having tested the Del Mar Avionics’ Holter monitors and ambulatory blood pressure monitors on the astronauts in orbit) and again retired after seven years as Professor of Medicine, Cardiology, University of Texas Medical Branch and is still interested in the advance of ambulatory patient physiological monitoring.

Dr. Corday in his lab, we proceeded to develop for him a special square-wave-modulated blood flow meter that would read the flow rate of blood in the heart’s canulated coronary artery of a large dog. This was an interesting and challenging electronics assignment for us and particularly for our young graduate physicist, William Thornton (Fig. 1) who was working in our engineering department. Together we designed, fabricated, and delivered a workable blood flow meter. With this new medical instrument tested and accepted, we launched a new direction of our company toward instruments for clinical cardiovascular medicine.

It is interesting to note that Dr. Corday was in the process of determining how the heart of a large animal might react to a partially blocked coronary artery, perhaps producing conditions similar to a human heart attack. He was also establishing information relative to open heart surgery! His discoveries would lead surgeons toward the possibility of open heart surgery on humans! Here was an important laboratory that called my attention to possibly larger and new opportunities for the Del Mar organization. Furthermore, I now had another strong reason to look toward the medical instrumentation field. Bill Thornton was so enamored with our work for Dr. Corday that he wanted me to promise to help support him with part-time engineering work during his vacation periods between sessions in earning an M.D. degree, specializing in cardiology, at the University of North Carolina, his alma mater, starting the following year. And I did!

Immediately after our experience with Dr. Corday, Bill Thornton and I said, "Let’s do some overnight tape recording of our hearts to view and explore the long term electronics of the ECG." So, we made single-channel, overnight ECG tape recordings, from awake-to-sleep to awake, on magnetic tape. We then wrote the tracings out in a voluminous fashion, a 100-foot track on ECG graph paper, to look for abnormalities.

Shortly after this, when I mentioned our tape recordings to Dr. Corday, he said, "Bruce, I have been approached several times by Norman J. Holter (Fig. 2), a physics researcher in Helena, Montana to..."
interest me in his human heart telemetry and ambulatory ECG recordings. He has been reporting and showing a special way of displaying the long-term arrhythmia action of the heart on a cathode ray tube. Think it over. Perhaps you should look at it and see if you could help him promote his project." Well, the next thing to do was to call the young physicist, Norman Jefferis Holter, and plan a visit to view his work in his laboratory in Helena, Montana. Later that month, with my patent attorney, Fred Smyth, I flew to Boise, Idaho and arrived in Helena, Montana by automobile from there and met "Jeff" Holter at his office in the former Helena railroad station, where the rail line dead-ended and the railroad station was no longer needed. Jeff’s father, an executive with the Mountain District Power Company, had arranged for Jeff to use the station as a research laboratory and also to interest local high school students in their physics education by having a nighttime high voltage crackling discharge of lightning between various large metallic spheres and ground rods, as well as to show other physical displays of magnetic attraction and earth’s gravity.

Fred Smyth and I were impressed with Jeff’s work, and offered to cooperate with him in the development of clinically acceptable instrumentation that we would design, manufacture, and market to the medical community. Jeff agreed to visit us in Los Angeles to discuss our offer, possible patent coverage and the status of the cardiovascular trademarks already held by his Holter Research Foundation.

At our next two meetings with Jeff Holter, patent and licensing contracts were signed, and the plans for action by Avionics Research Products Division of Del Mar Engineering Laboratories were outlined to Jeff and endorsed by him. We indicated that we would form a design team and would welcome his cooperation in this effort. We asked that one or more members of his research group be assigned to me when we started the design of a new airplane! So, it appeared the market was probably there and it was time to get on the move. I saw that Del Mar Engineering Laboratories was going to have to finance the entire first phase development for several years from the earnings from our sales of defense products to the US Air Force and US Navy.

In several phone calls to Helena, Montana in early 1962, Mr. Smyth, our patent attorney, called Jeff Holter’s engineer, Wilford R. Glasscock, who had been named co-inventor with Jeff Holter on their developments in ECG recording and ECG display. Mr. Glasscock transmitted to Mr. Smyth the essential engineering data to support a US patent application for ownership by the Holter Research Foundation. The patent application was filed on July 6, 1962, and 3 years later, on November 2, 1965, issued as US Patent Number 3215136 (Fig. 3). After the Holter Research Foundation patent application was prepared, several pieces of Holter prototype hardware were delivered to us at Los Angeles International Airport. I assigned our new ECG Recording and Data Reduction Project to our engineering department under Vice President Clifford Sanctuary and Chief Engineer Ray Cherry,
The History of Clinical Holter Monitoring

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The History of Clinical Holter Monitoring

Figure 3. Copy of one page of N.J. Holter’s patent (no. 3215136) that was issued on November 2, 1965.

with project engineers Don Anderson and Bill Thornton. Other important performers on the engineering team, such as Dave Squires from Helena, Montana, who came on board much later, were particularly important as we switched into computer-based hardware with heavy dependence on sophisticated, specialized software.

Del Mar’s engineering activity with Ambulatory ECG Monitoring and Display instrumentation had started in 1961 with production and deliveries commencing in 1963. By the end of the decade, we had delivered over 200 Holter Monitoring Systems. These initial systems were supported by hundreds, and then thousands, of ECG tape recorders featuring multichannel and multiday operation.

The various models, many will recall, carried both Del Mar-trademarked names and those that had been trademarked earlier by the Holter Research Foundation, namely, the Electrocardiocorder®, AVSEP®, and Arrhythmigraph®. We then followed with Electrocardiocharter®, Composite Electrocardioscanner®, Model 655 Dynamic Electrocardioscanner®, Models 660, 660A, and 660B Dynamic Electrocardioscanner®, Model 1000 Trendsetter® I, Model 2000 Trendsetter® II, Model 750 Innovator®, Model 9500 Evaluator® I, and Model 9500A Evaluator® II. Over the years, Del Mar converted production to new engineering models on an average of every 3–4 years through to the end of the century.

The most recent Holter Monitoring instrumentation systems marketed by Del Mar Medical Systems LLC after the year 1999 were: Model 363 AccuPlus®, Model 563 StrataScan®, and Model DS-90 DartScan®.

Innovations during this period were Micro Potential Analysis® (MPA) and Spectral Turbulence Analysis® (STA), and Heart Rate Variability (HRV), plus a variety of other enhancements which extended the initial ambulatory ECG monitoring concept.

In 2001, the development of the smallest solid state digital Holter recorder, with full fidelity and multiday capacity, was completed and introduced to the market. We called this the “Aria Impresario®.”

In 2002, work began on the newest generation “Impresario” data reduction, display, and report generation system. It is estimated by Del Mar Avionics that by the end of year 2002, our Holter Monitoring instrumentation system deliveries for the 40-year period, 1962 through 2002, totaled over 10,000 units! Our Holter Monitoring recorder deliveries had by then reached 40,000–50,000 units!

Looking back over the years that the various Holter Monitor models were designed and produced by Del Mar Avionics, we see a continual upgrade of our US patent applications based on their novel, breakthrough features. The physicians associated with the Del Mar Avionics medical product patents were either employees or consultants, or licensors of their inventions to Del Mar Avionics. One in particular became a long time consultant to those Del Mar Avionics engineers working on medical instrumentation. That physician,
Dr. Harold L. Kennedy, started working with us in the period 1970–1975, focusing his attention heavily on Holter Monitoring test results and techniques. He became active in the International Society for Holter and Noninvasive Electrocardiology (ISHNE), and in 1981 published his very well received book, *Ambulatory Electrocardiography Including Holter Recording Technology* (Lea & Febiger, Philadelphia, 1991). Dr. Kennedy's book has become a great reference text for its basic cardiology interface with monitoring the heart over long periods, and also as a source for "References" to prior and contemporary articles published on the Holter Monitoring subject.

A multitalented engineer and physician, cardiologist George Kelen made significant contributions to enhance the application and clinical value of Holter Monitoring. As a consultant to Del Mar, he led the development of a recorder that stored implanted pacemaker function and the subsystem that analyzed pacemaker performance, an important adjunct capability of Holter Monitoring. In 1988, Dr. Kelen developed Micro Potential Analysis software for incorporation in the scanning process of ambulatory ECG data. In 1991, he developed software for the analysis of spectral turbulence in the recorded ambulatory ECG. His work resulted in the issuance of our five US patents covering these unique inventions.

Another consultant to Del Mar Avionics, while we were designing and marketing exercise equipment including treadmills and ergometers, was Dr. Myrvin H. Ellestad at Long Beach Memorial Medical Center, California. His book, entitled *Stress Testing, Principles and Practice*, is now in its fifth edition [Oxford Press, 2003]. Dr. Ellestad taught us to better understand subjects such as ST depression, stress-induced arrhythmia, silent myocardial ischemia, and the safety requirements in controlling reasonable limits in exercise levels. He also taught us of the importance that cardiovascular implants, the battery-powered heart pacemakers and defibrillators have attained (in cardiac practice), not only for the implants, but also for the follow-up practice required to regularly check the long-term in vivo performance of these devices.

We have mentioned briefly the activity of the International Society of Holter and Noninvasive Electrocardiology, ISHNE. ISHNE has been a valued partner to Del Mar Avionics and to cardiologists worldwide for its informative publications since it was founded by Shlomo Stern in 1988. ISHNE has served to extend cardiology teaching, to recognize and honor the authors of a continual educational sharing of cardiovascular research and discoveries. It is a continuing responsibility to support ISHNE. Thank you, Shlomo Stern, for your years of service and, thank you, Arthur Moss, for your dedication to the current direction of ISHNE.

Our working relationships with cardiologists worldwide supporting Del Mar Avionics over the years recently attracted the attention of a publicly owned company in Europe, the Ferraris Group, plc, based in London. The Ferraris Group had expansion plans and had recently acquired the Reynolds Medical Ltd in Hertford, UK. The Ferraris Group had in mind combining Del Mar Medical Systems LLC with Reynolds Medical Ltd and calling it Del Mar Reynolds Medical Systems. An offer was made, negotiated and the sale of Del Mar Medical Systems was completed on January 1, 2003.

In years ahead, the Holter Monitoring instrumentation product line obviously faces a mature market from the manufacturer’s standpoint, but the fundamental need is still there! Technology will drive it forward! We will all benefit from the lower operating costs and greater reporting speed that such technology advancements will produce.