

A Brief History of Remote Cardiac Monitoring

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KEYWORDS

- Cardiac rhythm • Remote monitoring • Holter monitor • Transtelephonic monitoring
- Intermittent recorders

KEY POINTS

- Remote monitoring (RM) is an evolving technology that has already transformed the concept of cardiac rhythm monitoring.
- Clinical studies are now underway to determine the validity of remote monitor with respect to patient outcome efficacy and societal efficacy.
- Beginning with the advent of the Holter monitor and progressing to today's fully automated remote interrogation systems, RM offers the clinician an unprecedented amount of data and responsibility.

Remote cardiac monitoring refers to cardiac monitoring that is not conducted in clinical settings such as a hospital, clinic, or doctor's office. Multiple aspects of cardiovascular (CV) physiology can be monitored, including ambulatory blood pressure, ischemia, QT interval, heart rate variability, weight, blood pressure, cardiac rhythm, and volume status, to name a few. This article focuses on the history of cardiac rhythm monitoring, with an emphasis on the remote monitoring (RM) of cardiac rhythm management devices (CRMDs), including permanent pacemakers, implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy devices, and implantable loop records (ILRs). Although they were conceived during different decades, the technologies of Holter monitoring, transtelephonic monitoring (TTM), event monitors, and RM have all advanced in parallel with each other and along with advances in computer (storage and analysis) and communication technologies. In addition, current technology

is blurring the lines between these previously distinct diagnostic technologies. Consider for example, the Holter monitor, capable of recording continuously for up to 72 hours. Mobile cardiac outpatient telemetry (MCOT, CardioNet Inc) is a type of event monitor that can provide similar recording for more than 1 week. New wireless technologies, such as wireless LAN and sensor networks, for telecardiology purposes give new possibilities for monitoring of vital parameters with wearable biomedical sensors as well as for CRMDs. Patients now have the freedom to be mobile and still be under continuous monitoring.¹

EARLY HISTORY

External cardiac monitoring begins with the British physiologist, Dr Augustus Waller M.D. who published the first electrocardiogram (ECG) in 1887 (**Fig. 1**). Dr Waller's simple apparatus used a mercury capillary electrometer to measure fluctuations

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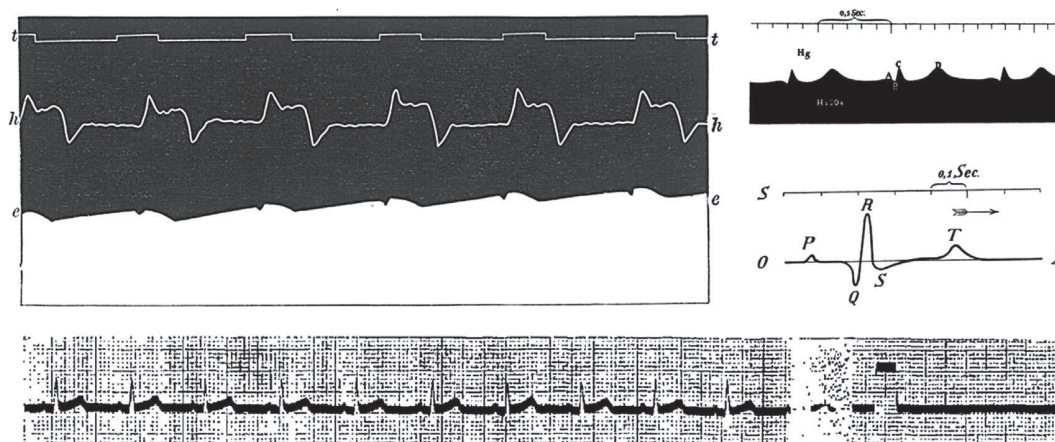


Fig. 1. Top left panel: first-published ECG using the capillary electrometer. The bottom waveform in white reflects measured deflections representing electrical activity. Top right panel: Einthoven's ECG recordings using capillary electrometer. Deflections of the electrometer waveform were referred to by letters A–E. Middle panel: correction of the capillary electrometer measurements using Einthoven's calculations allowed determination of a more accurate potential waveform. The corrected deflections came to be known by the letters P–T that persist to today. Bottom panel: ECG recordings using the refined string galvanometer, which allowed for potential measurements with a much faster frequency response and look much closer to modern ECGs. (From Waller AG. A demonstration on man of electromotive changes accompanying the heart's beat. *J Physiol* 1887;8:229–34; and Einthoven W. Die galvanometrische Registrierung des menschlichen Elektrokardiogramms, zugleich eine Beurteilung der Anwendung des Kapillar-Elektrometers in der Physiologie. *Pflügers Arch* 1903;99:472–80.)

in potential across a pair of leads, one strapped to the front of the chest and one strapped to the back.² Even with such an apparatus, his initial recordings showed deflections in surface potential and were able to demonstrate that electrical events preceded mechanical events by a measurable delay. Public demonstrations of Waller's work often involved his famous patient "Jimmy", his bulldog who would patiently stand with feet in jars of saline attached to electrodes. Among the observers of these demonstrations was the Danish physiologist Dr Willem Einthoven, considered by many to be the father of electrocardiography. Einthoven recognized many of the limitations of the capillary electrometer and developed several important advancements, including calculations to correct for waveform distortions caused by the electrometer and refinement of the string galvanometer (see **Fig. 1**),³ originally invented by Ader.⁴ These and other improvements by Einthoven led to the development of the first practical electrocardiograph (ECG) and his receiving of the Nobel Prize in Medicine in 1924 for the invention of the practical ECG.

MODERN HISTORY

Further maturation of technology allowed miniaturization of many of the components. Einthoven's original apparatus involved large instruments

weighing several hundred pounds and necessitated multiple operators. In the succeeding years, the ECG was commercialized, miniaturized, and became a useful hospital tool in patient care.

By 1949, biophysicist Dr Norman "Jeff" Holter of Montana was attempting the first truly RM of cardiac surface potentials.⁵ His initial device transmitted a 2-lead ECG by radio signals and was housed in a crude backpack weighing almost 85lbs (**Fig. 2**).⁶ Within a few years, this device had been miniaturized down to a 2.6lb amplifier and transmitter.⁷ Within 10 years, further miniaturization and refinements became possible with the start of the transistor age, and the device eventually abandoned radio transmission for local data storage on magnetic tape. By 1961, the Holter monitor was emerging a potential tool, and it quickly was adopted into clinical use where it became a lasting instrument for ambulatory monitoring. The first commercially available ambulatory ECG device was manufactured in 1962 (deliveries commencing in 1963) by Del Mar Engineering Laboratories under the name Avionics Research Products Corporation.⁸ Once a recording was made, it could be played back and analyzed at 60X speed allowing a 24-hour recording to be analyzed in as little as 24 minutes. Magnetic tapes could record only 2 channels that were prone to recording limitations such as wow, flutter, tape head misalignment, as well as mechanical malfunctions. These

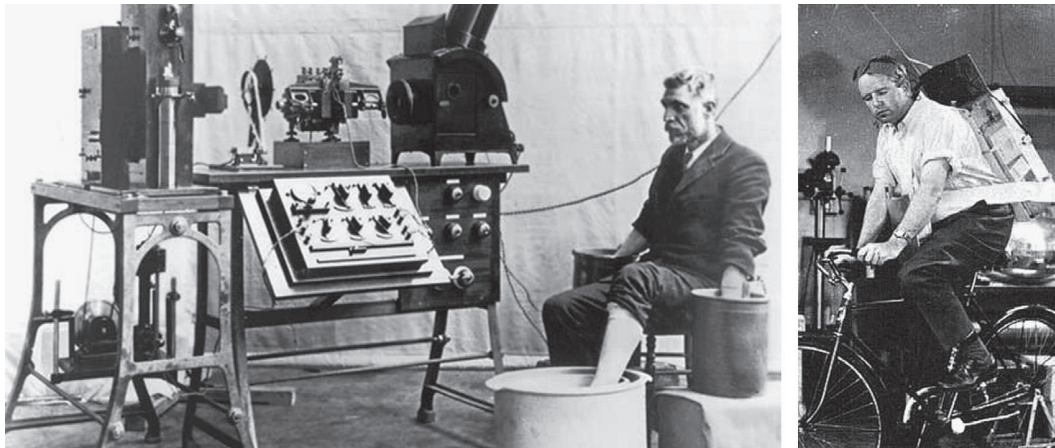


Fig. 2. Left: miniaturized commercial “table top” model of ECG apparatus using Einthoven’s string galvanometer. Right: the first Holter monitor transmitted and ECG using radio signals. It weighed roughly 85 lbs and could be worn as a backpack. ([Left]: From Barron SL. Development of the electrocardiograph in Great Britain. *Br Med J* 1950;1:720; with permission. [Right]: Lot 18 Holter Research Foundation Photo Collection, Montana Historical Society Photograph Archives. Courtesy of Montana Historical Society, Helena, MT; with permission.)

issues were eliminated with the use of a PCMCIA type II digital recorder that acquired three leads of 8-bit data on a removable flash memory device. As the cost and size of greater memory capacity has decreased, digital recording has improved significantly in a few short years. Capable of recording as many as 12 leads, digital recorders can sample and store at very high rates with remarkable resolution for very long periods of time. Digital devices not only improve the capacity and accuracy of the recording but also allow for interface to more sophisticated software analysis. These software algorithms are used to reject artifact and screen for arrhythmias and other findings to flag for review by the technician and physician. More complex analyses such as heart rate variability can be performed as well. Although the Holter monitor remains an important clinical tool in today’s practice, it is still limited in the overall duration of its recording. If the patient’s symptoms are infrequent, a Holter monitor becomes an ineffective diagnostic tool. Another disadvantage of Holter monitors is the need to return the device for processing and analysis after each use. Even if a clinical event occurred during the study, the data needs to be screened, reviewed and correlated to the event. The data analysis is not done in real-time. Newer technologies include wearable patches that record the ECG for up to 7 days; they can be removed from the patient’s body and mailed in for analysis.

TTM is a technology introduced in the early 1970s and has been, until this decade, the predominant method of remote pacemaker follow-up. It is

also the basis for arrhythmia surveillance for the first generation of patient-activated event monitors.⁹ This technology converts ECG information into sound, to communicate over telephone lines to a decoding machine, which changes the sound back into a “rhythm strip”. TTM is discussed again later in this article.

Event monitors are another category of devices that are used to remotely assess cardiac rhythm abnormalities. **Box 1** summarizes the categories of available devices. Devices are categorized according to whether they monitor cardiac rhythm intermittently or continuously and whether they are worn externally or implanted. The technologies that have resulted in the advancement of these devices are the same as those that are responsible for the advancement of the Holter monitor. These include digital recording and storage, transtelephonic transmission, and software analysis of data.

Box 1 **Categories of event monitors**

Patient-activated or event-activated devices

- Presymptom memory loop recorders (attended and unattended)
- Implantable presymptom memory loop recorders
- Post-symptom recorders (attended or unattended)

Real-time continuous attended cardiac monitoring

The largest category in use today is the patient-activated/event-activated intermittent recorders (presymptom loop and post-symptoms recorders). Data from these devices are transmitted by phone to a doctor's office, clinic, hospital, or an independent diagnostic testing facility (IDTF). Service providers for these devices offer attended monitoring through their IDTFs. The standard external loop recorder (ELR) also uses memory loop recording capable of storing several minutes of data until it requires transmission to a monitoring center. The patient must signal an event to acquire data. Asymptomatic episodes (ie, some patients with atrial fibrillation) need an auto-trigger ELR. These also have a looping memory system. These recorders frequently auto-activate for false events or artifact, filling the memory and requiring the patient to perform frequent transmissions. Both these types of ELRs require the patient to perform a transtelephonic transmission to the monitoring center. Post-symptoms event recorders are hand-held devices that have no chest electrodes. These monitors do not have the memory loops of presymptoms recorders and can therefore record the rhythm that occurs only at trigger. The patient applies the monitor directly to the chest during the symptoms. Although they provide good correlation to patient symptoms and rhythm, they can miss clinical arrhythmias if the patient does not perform or cannot perform the needed steps. Most monitors are placed over the patient's chest, but several monitors exist that record the ECG from wrist bands similar in location to wearing a wristwatch.

Real-time *continuous* attended remote cardiac monitoring systems automatically record and transmit arrhythmic event data from ambulatory patients to personnel at a clinic, hospital, or, in most cases, an IDTF. The technicians at these IDTFs are trained to interpret cardiac arrhythmias and contact clinicians and/or patients based on preset parameters. The first generations of these monitors require the patient to take the device to a base station in the patient's home, which is linked to a land-based phone line. Newer devices have a built-in cellular telephone that automatically transmits events to the monitoring center virtually regardless of the patient location. The ability to respond immediately to clinical events as they occur is the major advantage of these systems.

ILRs perform the same function of external recorders but are implanted and are typically used for much longer periods of time. The Transoma Medical Sleuth was a programmable device with a wireless system that could transmit ECG data to an RM center. The Transoma Medical Co went out of business before this product reached

significant clinical use. The currently available ILRs are manufactured by Medtronic Inc (Reveal) and St. Jude Medical Inc (Confirm). Neither of these devices has wireless technology and requires an in-office interrogation or a home RM unit (Medtronic Carelink or St. Jude Medical Merlin).

Initial implanted cardiac pacemakers required very close follow-up, including at least weekly 12 hour sessions for recharging of batteries via external induction. Improvements in battery technology allowed for long-term ambulatory devices. Almost immediately, methods for RM of cardiac events and device functions were explored. Initial efforts consisted of devices similar to Holter monitors that provided short-term recording of ambulatory ECGs. The recorded data were then reviewed in an office visit where it could be reviewed at 60x speeds. By the 1970s, TTM was providing an alternate means of monitoring.¹⁰ Initially, the use of TTM was generally applied only for scheduled checks for monitoring the longevity of implanted pacemakers or for confirmation of symptomatic arrhythmias during checks initiated by the patient.¹¹ Although the clinical use of TTM further expanded to eventually include detection of more subtle pacemaker malfunction than battery depletion, including problems with sensing or capture, lead malfunctions, and even transtelephonic device programming,¹² TTM's adequacy as the sole form of follow-up for the first years following implantation of a pacemaker has been questioned.¹³ TTM ICD interrogation was first reported in the early 1990s.¹⁴ Transmitted data included programmed VT/VF detection criteria and therapies, battery status, charge time, episode counters, and therapy logs. In this study, there was complete accuracy of TTM data when compared to data obtained during standard in-office follow-up. Despite improvements in the technology including expansion of TTM use to ICDs (uncommon), the real-time nature of TTM interrogation limited it as a useful tool only for detection of pacemaker malfunction and significant arrhythmias.¹⁵ Further studies have called into question its utility in detecting more than pulse generator failure, battery depletion, and lead failure¹⁶ and have demonstrated its inferiority compared with in-office visits.¹⁷ Thus, the data supporting the efficacy of TTM for pacemaker and ICD follow-up are mixed. The other inherent disadvantage of TTM is its reliance on the active cooperation of the patient who has to place a special device over his/her pacemaker or ICD.

In the 2008 PREFER clinical trial, the efficacy of the emerging technologies for RM compared favorably to TTM. This study concluded that

remote pacemaker interrogation follow-up detects actionable events that are potentially important, more quickly and more frequently than TTM recordings. It also found the use of TTM for pacemaker follow-up to be of little value except for battery status determinations.¹⁸

MODERN REMOTE MONITORING

A combination of advancements within pacemakers and ICDs, cellular technology, and internet technologies have all driven and contributed to the development of the modern RM systems. Both pacemakers and ICDs are now able to store large amounts of arrhythmia data (ie, atrial fibrillation burden) and physiologic data (ie, transthoracic impedance: Optivol Medtronic, Inc) as well as basic information about lead integrity and device status. The usefulness of the information is dependent on its timely availability to clinicians.

Most of the CRMDs are also enabled with a radiofrequency transmitter that facilitates both in-office and RM. Medical Device Radiocommunications Service (MedRadio) dates back to 1999 when the FCC established the Medical Implant

Communication Service (MICS). At that time, the FCC set aside 3 MHz of spectrum at 402 to 405 MHz for medical implant devices. This allowed for the development of the first RM system in 2001, Biotronik's Home Monitoring (HM). That same year, the first pacemaker capable of RM was implanted at Stanford University. By 2003, the first internet-based RM system was introduced along with compatible wireless and cellular transmitters. By 2006, the Centers for Medicare and Medicaid Service (CMS) approved a favorable reimbursement structure for RM and follow-up further incentivizing the acceptance of RM. In 2009, the FCC created the Medical Device Radiocommunications Service (MedRadio) in the 401 to 406 MHz range. The creation of the MedRadio Service incorporated the existing MICS spectrum at 402 to 405 MHz and added additional spectrum at 401 to 402 MHz and 405 to 406 MHz for a total of 5 MHz of spectrum for implanted devices as well as devices worn on the actual body.

Table 1 summarizes the currently available RM systems according to manufacturer. Each system is proprietary and works only with the associated devices. Biotronik's HM is the most extensively

Table 1 Remote monitoring systems from major manufacturers				
	Biotronik	Medtronic	Boston Scientific	St. Jude Medical
Name	Home Monitoring	Carelink	Latitude	Merlin House Call Plus
FDA approval	2001	2005	2006	2007
Portable/ stationary	Portable	Stationary	Stationary	Stationary
Operation	Automatic	Patient-initiated and automatic	Patient-initiated and automatic	Automatic and patient-initiated
Devices monitored	ICD, PPM, CRT-P, CRT-D (all wireless)	ICD, CRT (PPMs and ILRs required wanded download)	ICD, CRT (no PPM) Wanded- operation and wireless	ICD, PPM, CRT-P and CRT-D (all wireless)
Technology	Cellular or landline	Landline	Landline	Landline or cellular
Event notification	Website; fax; e-mail; SMS	Website; phone; e-mail; SMS	Website; fax; phone	Website; fax; phone; SMS
Alert programming	Remote	Requires patient presence	Remote	Requires patient presence
Heart failure sensor	HRV	OptiVol	Weight, blood pressure	HRV

Abbreviations: CRT-D, cardiac resynchronization defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; FDA, Food and Drug Administration; HRV, heart rate variability; ICD, implantable cardioverter-defibrillator; PPM, pacemaker; SMS, short message service.

Adapted from Ellenbogen K, Wilkoff B, Lau CP, editors. Clinical cardiac pacing, defibrillation, and resynchronization therapy. 4th edition. Philadelphia: Saunders; 2011; with permission.

studied system (see later discussion). There are significant differences between the systems with respect to patient involvement, alerts, transmission technology, and portability. Once data are transferred from the patient's device to the transmitter or base station, it is encrypted and uploaded via landline or cellular line to a secure central server maintained by the individual manufacturer. The standards for transmission are exceptionally high with no significant loss of data packets.¹

One fundamental difference in the available systems is the degree of automation. This is a feature that truly distinguishes RM from scheduled TTMs. Automatic RM was pioneered by Biotronik (HM). The patient needs to be within 6 feet of the transceiver for it to link with the device and receive data on a scheduled basis. The data are then automatically transferred via cellular technology and sent to the physician on a prioritized basis. Customizable alerts can be programmed individually. Data acquisition and transmission are performed completely independent of the patient and physician. HM is also the most extensively studied system with clinical data supporting its reliability, accuracy, and early notification ability. It has also been shown to have a low energy cost with respect to battery depletion and is not susceptible to electromagnetic interference. The transceiver is a fully mobile unit and will work worldwide.

In contrast, Medtronic Inc, Boston Scientific Inc, and St Jude Medical Inc each have RM systems that require some degree of a patient-initiated follow-up. The patient must interact with the transceiver (apply the wand and/or initiate interrogation) and coordinate with clinic personnel on a scheduled basis.

As mentioned earlier, HM is an example of a clinically, well-studied RM system. In 2010, The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) trial tested the hypothesis that remote home monitoring with automatic daily surveillance (HM) is safe and effective for ICD follow-up and enables rapid physician evaluation of significant events.¹⁹ In total, 1339 patients underwent 2:1 randomization to HM or conventional follow-up. Follow-up checks occurred at 3, 6, 9, 12, and 15 months after implantation. HM was used before office visits at 3 and 15 months in the HM group. At 6, 9, and 12 months, HM not only was used but also was followed by office visits if necessary. Conventional patients were evaluated with office visits only. Scheduled office visits and unscheduled evaluations, incidence of morbidity, and time elapsed from first event occurrence in each patient to physician evaluation were tracked for each group. The primary goal of the study was to assess the number of total in-hospital device

evaluations in HM compared with conventional care and to assess the safety of the remote follow-up method. RM reduced total hospital encounters for device interrogation by 45%. More than 90% of scheduled checks were nonactionable and did not necessitate an in-person device clinic encounter. The secondary endpoint compared detection times of clinically significant events, assessed by time from event onset (from device diagnostics) to physician evaluation of first occurrence of arrhythmia (AF, VT, VF, and SVT) in individual patients. Detection was advanced by more than 30 days compared to the conventional group. It is data from this trial that led the FDA to issue the unique and specific labeling to the Biotronik HM system as the only RM approved to replace in-office device follow-up.

Other clinical studies support the use of RM. In 2010, The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial looked at the value of wireless RM with automatic clinician alert.²⁰ The primary objective was to determine if wireless RM with automatic clinician alerts reduces the time from a clinical event to a clinical decision in response to arrhythmias, CV disease progression, or device-related issues compared to patients receiving standard in-office care. The secondary objective was to compare the rates of CV health care utilization between patients in the remote and in-office groups. Health care utilization data were defined as all CV-related hospitalizations, emergency department visits, and clinic or office visits. This study was a multicenter, prospective, randomized evaluation involving 1997 patients from 136 clinical sites who underwent insertion of an ICD (including cardiac resynchronization therapy devices) and were observed for 15 months. The overall findings of the study were similar to those of the TRUST trial. This study demonstrated that wireless RM allows clinicians to make clinical decisions 17.4 days sooner when compared with the in-office group. RM patients with atrial tachycardia/atrial fibrillation events had a reduced median time from arrhythmia onset to a responsive clinical action (3 days vs 24 days). The health care utilization data revealed a decrease in mean length of stay per cardiovascular hospitalization from 4 days (in-office group) to 3.3 days in the RM group ($P<.002$). The Medtronic Carelink system was used in this study and, unlike HM, is an entirely patient-initiated system. Once the system was activated, a successful transmission led to a clinician viewing the data within 1.5 days 70% of the time. This study highlights the need for the supporting infrastructure within individual clinical setting that is adequate to respond to the incoming data.

The impact of RM on mortality was studied in the ALTITUDE trial.²¹ This project was an independent clinical study initiated in 2008 and prospectively analyzed data from Boston Scientific's LATITUDE RM system. The study asserted that there is a mortality benefit to patients followed on the RM system compared with those undergoing traditional in-office follow-up. Despite its novel conclusions, this study has major limitations preventing its generalization. Among these limitations are the absence of randomization and major lack of clinical profile data, specifically comorbid conditions.

There are many unresolved questions regarding RM including those related to quality assurance as well as medical-legal issues. Data currently reside on servers owned by the manufacturers. Data ownership and privacy issues are unresolved. Practical issues related to office staffing and the monitoring of incoming data need to be decided at the individual clinic level. The HRS expert consensus statement regarding the monitoring of CRMs address many of these issues, and the reader is referred to this document for complete details.²²

SUMMARY

As with all technologies it is interesting to consider remote cardiac monitoring in the conceptual framework proposed by Fryback and Thornbury.²³ This 6-tiered hierarchical model suggests an approach to analyze the efficacy of a diagnostic technology. The 6 levels are

- Level 1: Technical efficacy
- Level 2: Diagnostic accuracy efficacy
- Level 3: Diagnostic thinking efficacy (percentage of patients for whom the test was helpful in making a diagnosis)
- Level 4: Therapeutic efficacy (percentage of patients for whom the test resulted in a change in management)
- Level 5: Patient outcome efficacy (percentage of patients improved with the test than without the test)
- Level 6: Societal efficacy (cost-effectiveness analysis from a societal viewpoint)

RM is an evolving technology that has already transformed the concept of cardiac rhythm monitoring. Despite the many unanswered question regarding RM, clinical data presented earlier establish its progression solidly through level 4 of the Fryback framework. Clinical studies are now underway to determine the validity of RM with respect to patient outcome efficacy (level 5) and societal efficacy (level 6).

RM of cardiac rhythm has advanced remarkably since the days of Waller and Einthoven. Beginning with the advent of the Holter monitor and progressing to today's fully automated remote interrogation systems, RM now offers the clinician an unprecedented amount of data and responsibility. The efficacious use of this data is a subject for another article in medical history.

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