ILR 과 Device F/U 수가와 외국의 remote monitoring 현황 및 수가

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Current State of CIED Remote Monitoring

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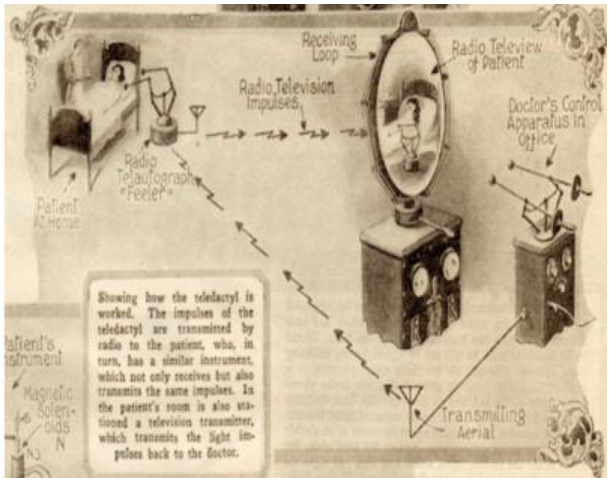
Hugo Gernsback, Science and Invention Magazine, February 1925



"The Teledactyl (Tele, far; Dactyl, finger — from the Greek) is a future instrument by which it will be possible for us to 'feel at a distance.' This idea is not at all impossible, for the instrument can be built today with means available right now. It is simply the well known telautograph, translated into radio terms, with additional refinements. The doctor of the future, by means of this instrument, will be able to feel his patient, as it were, at a distance…The doctor manipulates his controls, which are then manipulated at the patient's room in exactly the same manner. The doctor sees what is going on in the patient's room by means of a television screen."

First Trial of ECG remote monitoring

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.)

By 1949, Dr Norman Jeff Holter was attempting the first truly remote monitoring of cardiac surface potentials.

The first commercially available ambulatory ECG device manufactured in 1962 by Del Mar Engineering Laboratories.

Technology in use for Remote Monitoring

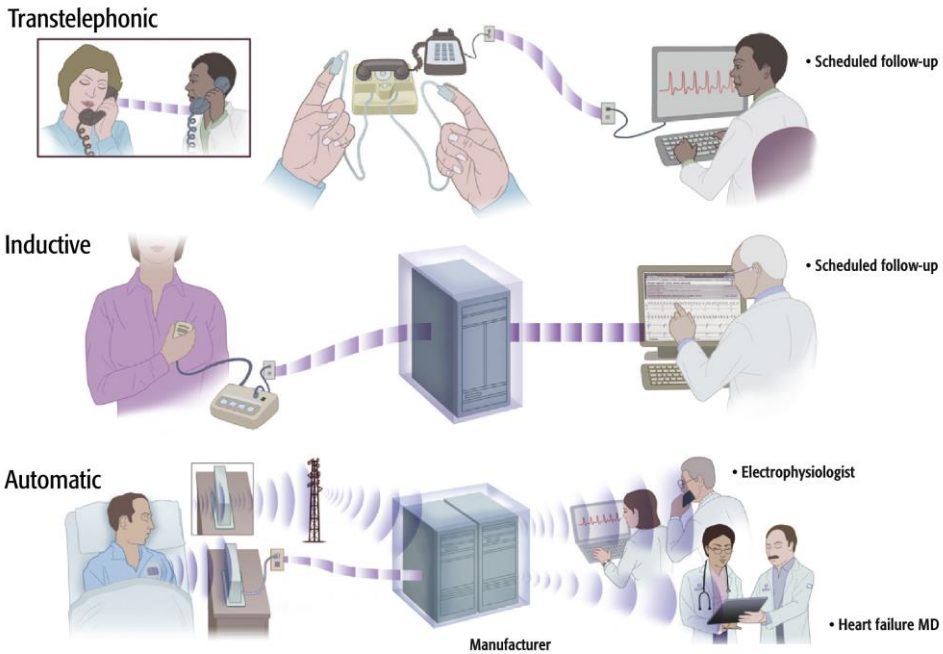


Figure 1 Technologies in use.

Remote Interrogation vs Remote Monitoring

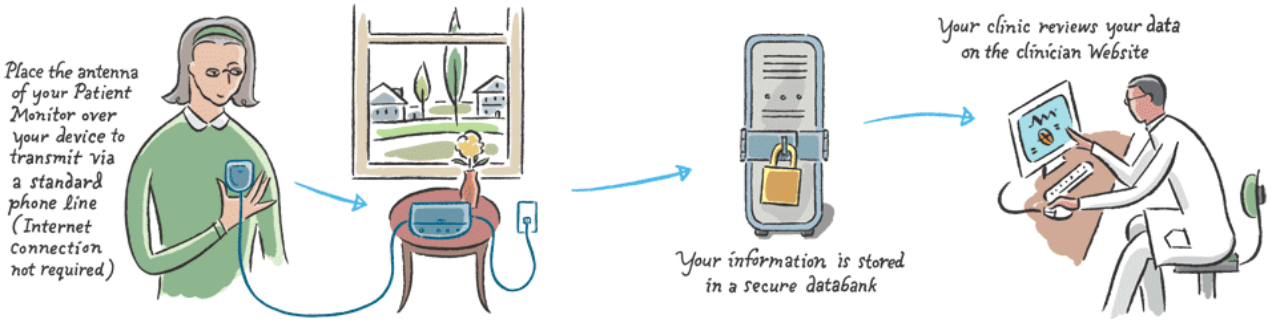
- Remote Interrogation (RI)
  - routine, scheduled, remote device interrogations structured to mirror in-office checkups
  - Practically all information obtained during an in-office device checkup can be obtained remotely, except for the pacing capture threshold.
- Remote Monitoring (RM)
  - the automated transmission of data based on prespecified alerts related to device functionality and clinical events.
  - This provides the ability for rapid detection of abnormal device function and/or arrhythmia events.

Remote Cardiac Device Monitoring Systems

- Systems commonly available in the US:
  - Medtronic Carelink®
  - St. Jude Merlin™@Home and HouseCall Plus™
  - Biotronik CardioMessenger®
  - Boston Scientific LATITUDE® system

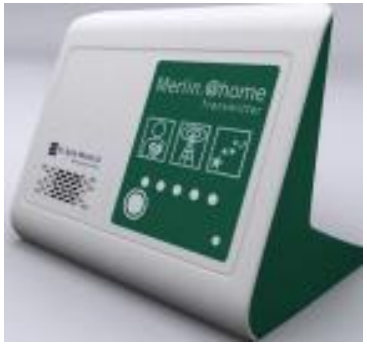
Medtronic CareLink Network

- The patient monitor enables you to “connect” your implanted device to your clinic via a standard phone line.
- Available for Medtronic ICDs, CRT, pacemakers and implantable cardiac monitors in the United States.



St. Jude Merlin@Home

- The patient monitor enables you to “connect” your implanted device to your clinic via a standard phone line.
- For use with Current™ RF ICD and Promote™ RF CRT-D devices.



St. Jude Housecall Plus

- The patient monitor enables you to “connect” your implanted device to your clinic via a standard phone line.
- For use with Atlas™ and Epic™ ICDs and Atlas HF and Epic HF CRT devices.

www.sjm.com/

Biotronik CardioMessenger

- A portable unit that receives data from the implanted device. It is the link that connects you to the Biotronik service center.
- Available for Biotronik ICDs, CRT and pacemakers in the continental United States and in over 50 countries.

www.biotronik.com/en/us/

Boston Scientific LATITUDE System

- The patient monitor enables you to “connect” your implanted device to your clinic via a standard phone line.
- Available for Boston Scientific ICDs and CRT devices in the United States, Puerto Rico and the Virgin Islands.

www.aboutlatitude.com

Remote Interrogation Combined With Remote Monitoring: Clinical Benefits

- Nearly continuous monitoring
- Daily self-testing and event notification for out-of-bound parameters, which are not possible for wanded telemetry systems.

- Follow-Up Optimization and Patient Safety
- Patient Satisfaction and Quality of Life
- Device Surveillance
- Shock Reduction
- Disease Management

Clinical benefit by RM

- Follow-Up Optimization and Patient Safety
  - can reduce the volume of office visit by approximately 50% for patients with all types of CIEDs, without compromising safety and improving the early detection of clinically significant even
  - CONNECT trial
  - TRUST trial

Figure 2 Benefits of remote monitoring. CONNECT = Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision; TRUST = Lumos-T Safely Reduces Routine Office Device Follow-Up.

Clinical benefit by RM

- Patient Satisfaction and Quality of Life
  - RM showed a high rate of patient satisfaction such as
    - patient's perceived relationship with their health care providers
    - ease of use
    - psychological impact
    - ability to maintain follow-up compliance
  - Remote follow-up reduces in person evaluation (IPE) costs such as travel, time off from work, and the interruption of daily activities.

Clinical benefit by RM

- Device Surveillance
  - RM alerts practitioners to changes in lead or device function that would otherwise go undetected until the next scheduled IPE or RI
    - Trends in lead impedances
    - the number of mode switch events
    - ventricular arrhythmias
    - changes in Rwave and P-wave amplitudes,…
  - The advantages of this mechanism have been demonstrated in large randomized trials (eg, TRUST trial) and supported by observational data in mega-cohort analyses (eg, ALTITUDE trial and MERLIN trial).

Clinical benefit by RM

- Shock Reduction
  - The early detection function of RM for clinical events such as atrial fibrillation with rapid ventricular response rates, T-wave oversensing or electromagnetic interference, or device malfunction, enables faster intervention to reduce the risk of unnecessary ICD shocks.

  - The ECOST study evaluated ICD therapy events and reported a significant reduction in inappropriate therapy for patients assigned to the RM arm. Over 27 months, the incidence of inappropriate shocks was 5.0% in the patients randomized to the RM group compared with 10.4% in the standard group (P = .04).

Clinical benefit by RM

- Optimization of Device Longevity

- Disease Management
  - Atrial Fibrillation
    Stroke Risk Associated With Device-Detected Atrial Fibrillation.

  - Heart Failure

  - Channelopathies

  - Implantable Loop Recorders

Atrial Fibrillation (AF) Detection by RM

- AF was responsible for more than 60% of alerts in pacemakers and CRT-Ds and for nearly 10% of alerts in dual-chamber ICDs.
- About 90% of AF episodes that trigger alerts are asymptomatic.
- Early detection of AF by RM can enable intervention to avoid ICD inappropriate therapy, heart failure, and avoid loss of
  biventricular pacing. Early detection also provides additional
  time to consider whether to initiate anticoagulation therapy.

Stroke Risk Associated With Device-Detected Atrial Fibrillation.

- In the majority of study patients, recordings made up to 30 days before the thromboembolic events showed no atrial fibrillation episodes, indicating temporal relationship between atrial fibrillation and the thromboembolic event may not always exist.

- An interventional trial of starting and stopping oral anticoagulation based on RM detected AF burden failed to show any difference in stroke rates or all-cause mortality.

(IMPACT trial, EHJ 2015)

Legal Considerations

- The possible consequences of delayed action or inaction in response to alerts transmitted by RI and RM represent the most commonly cited concern on the part of caregivers.
- The current RM technology can warn of significant clinical problems within minutes, and most medical practices cannot respond immediately.
- Nonetheless, RM is becoming the standard of care, and as such there is risk of liability for not informing patients of the technology and its proven benefits.

Roles and Responsibilities of the Remote Monitoring Team Members

Table 4 Potential Topics to Cover in the Initial Patient Education and Patient Agreement/Contract

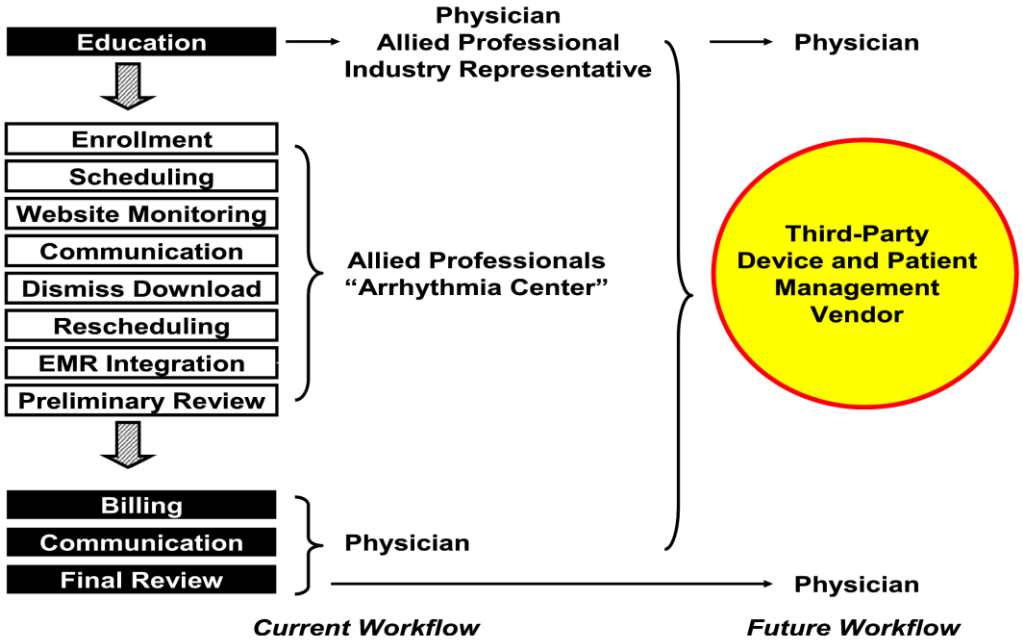
Overview of RM	• Explain the benefits and limitations. • Explain the frequency and types of monitoring.
What to expect	• Frequency of remote RI and RM. • RI and RM are not meant to be an emergency response system. • Indicate the hours of operation and the expected delay in responding to alerts (eg, next business day), as well as the operation (if any) during evenings, weekends, and holidays. • Expectations for in-person follow-up. • Expectations for the responsibilities of and the communication with CIED clinic staff.
Patient responsibilities	• Keep all contact information up to date. • Keep the clinic informed of other health care providers to whom reports should be communicated. • Inform the CIED clinic about extended travel. • Keep the clinic up to date on the medical condition and drug changes. • Maintain the function of the transceiver and appropriate landline/cellular communications. • Understand how to interface with RM equipment. • Show up for an IPE when an alert is triggered and when advised by the clinic staff.
Privacy	• All patient health data are kept private in accordance with local/national laws. • De-identified, aggregate data may be used for quality assurance and/or research purposes.
Consent	• Patient agrees to RM.

CIED = cardiac implantable electronic device; IPE = in-person evaluation; RI = remote interrogation; RM = remote monitoring.

Roles and Responsibilities of the Remote Monitoring Team Members

- Most importantly, RM requires dedicated allied professional resources to ensure the timely and complete review of transmitted information. This can be accomplished by a dedicated resource person or by assigning CIED clinic allied professionals to RM, with clear accountability for data review.

Third-Party Provider Responsibilities



Reimbursement

- Despite the scientific data supporting the cost-effectiveness
  of RI and RM, reimbursement for physician and practice expenses is lacking in many countries.

  only the United States and Germany recognizing full reimbursement for services rendered remotely.

  Even in countries that do not provide reimbursement, many health
  care providers have adopted the technology because of the
  resulting efficiency.

Reimbursement

- 호주: 대면진료 75불…
- 원격모니터링 66불 (일년에 두번 … 132불/년)
- ICD는 일년에 4번…400불/년 받을 수 있다.
-

- 독일: 40유로/년,
- 트랜스미터 값은 못 받고 있음…

Box 2
Reimbursement for remote monitoring

Technical reimbursement

- 93296 ($36)

  Interrogation device evaluations remote, up to 90 days; single, dual, or multiple lead permanent pacemaker (PPM) or ICD system, remote data acquisitions, receipt of transmissions and technician review, technical support and distribution of results

Professional reimbursement

- 93294 ($37; once per 90 days)

  Interrogation device evaluations (remote), up to 90 days; single, dual, or multiple lead PPM system with interim physician analysis, reviews, and reports

- 93295 ($66; once per 90 days)

  Interrogation device evaluations (remote), up to 90 days; single, dual, or multiple lead ICD system with interim physician analysis, reviews, and reports

- 93297 ($26; once per 30 days)

  Interrogation device evaluations (remote), up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal or external sensors, physician analysis, reviews, and reports

Remote monitoring in Asia-Pacific

Table **Remote monitoring of cardiac implantable electronic devices in major countries/regions in Asia-Pacific**

	Australia and New Zealand	China	Hong Kong	India	Japan	South East Asia
% Pacemaker with RM	15	1.7	<1	<1	5	<1
% ICD with RM	40	14.2	<5	<1	50	<1
% CRT/CRTD with RM	30	8.6	<10	<1	50	<1
Year started	2001	2009	2010	2009	2007	2012
No. of RM centers	120	250	9	NA	400	3
No. of Implanting centers	200	1200	24	NA	2000	NA
Data surveillance	Technicians Nurses Physicians	Industry Physicians	Industry Technicians Nurses Physicians	Physicians	Physicians Technicians	Technicians Physicians
Reimbursement	No	No	No	No	Yes	No
Additional cost (%) per unit	15	20	20	NA	5	20

Data shown are the maximum reported from any of the four providers of remote monitoring devices.
CRT, cardiac resynchronization therapy; CRTD, cardiac resynchronization therapy and defibrillator; ICD, implantable cardioverter defibrillator; NA, data not available; RM, remote monitoring.

년도별 심평원 진료행위 통계

삽입술 & 교체술													
심사년도		2010년		2011년		2012년		2013년		2014년		2015년	
분류	코드	환자수	총사용	환자수	총사용	환자수	총사용	환자수	총사용	환자수	총사용	환자수	총사용
ICM	E6551	14	14	8	8	6	6	17	17	11	11	16	16
박동기	O0203 O0204 O2004 O0205 O0206	2,845	2,847	2,919	2,929	3,152	3,154	3,704	3,737	3,930	3,971	4,037	4,065
ICD	O0211 O0212	416	428	479	486	579	583	722	734	885	888	1,121	1,127
계		3,261	3,275	3,398	3,415	3,731	3,373	4,426	4,471	4,815	4,859	5,158	5,192

① 전기적 분석_이식형 사건 기록기

분류번호	코 드	분 류	점 수
나725-3		이식형 사건 기록기 삽입 및 제거술 Implantation of Insertable Loop Recorder / Removal of Insertable Loop Recorder 주: 사용된 이식형 사건 기록기(Implantation Loop Recorder)는 별도 산정한다.	
	E6551	가. 삽입술	4,155.12
	E6552	나. 제거술	1,919.12
	E6553	다. 기능조정 및 심전도 분석	393.95
	코드신설	라. 기능조정, 심전도 분석 및 원격 모니터링 주.환자 한 명당 년 1회 대면진료 및 월1회, 6개월까지 원격모니터링 금액을 포함하여 산정한다.	1,181.85

② 전기적 분석_심박기 거치술

분류번호	코 드	분 류	점 수
너-872	EX872	가.심박동기 시스템의 전기적 분석 Electronic Analysis of Pacemaker System 주: 영구적심박동기 삽입 후 심기능 및 심조율의 변화에 따라 Pacing Mode를 조정하거나 시간 경과에 의한 Battery Life, Threshold, Integrity의 변화에 대해 적절한 System 분석 및 교정을 한 경우에 산정한다.	340.83
	코드신설	나.심박동기 시스템의 전기적 분석 및 원격 모니터링 Electronic Analysis of Pacemaker System with Remote Monitoring 주: 환자 한 명당 년 1회 대면진료 및 년 3회까지 원격모니터링 금액을 포함하여 산정한다.	1,022.49

③ 전기적 분석_심율동전환제세동기 거치술

		다. 분석 및 프로그램 재설정	
		Electronic Analysis of ICD System	
	O0213	(1) 심방 또는 심실 전극이 삽입된 경우	316.82
		Atrial or Ventricular Lead (Single Chamber)	
	O0214	(2) 심방 및 심실 전극이 삽입된 경우	340.83
		Atrial and Ventricular Lead (Dual Chamber System)	
	코드신설	라. 원격모니터링 분석 및 프로그램 재설정	
		Electronic Analysis of ICD System with Remote Monitoring	
		(1) 심방 또는 심실 전극이 삽입된 경우	950.46
		Atrial or Ventricular Lead (Single Chamber)	
		(2) 심방 및 심실 전극이 삽입된 경우	1,022.49
		Atrial and Ventricular Lead (Dual Chamber System)	
		주: 원격모니터링 환자 한 명당 년 1회 대면진료 및 년 3회까지 원격모니터링 금액을 포함하여 산정한다.	

Conclusion

- Remote monitoring have been demonstrated to reduce scheduled office visits, improved device management and disease management including heart failure admission.
- The new health care system is rapidly taking shape and, although no one can predict how it is going to evolve.
- Although delayed to adopt the remote monitoring system in Korea, we should prepare this new generation medicine preemptively.