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# Remote Follow-Up/Monitoring of Cardiac Implantable Electronic Devices

## Kardiyak İmplante Edilebilir Elektronik Cihazların Uzaktan Takibi ve Monitörizasyonu

**ABSTRACT**

Cardiac implantable electronic device (CIED) implantation is a diagnostic and therapeutic method that is being employed on a growing number of patients globally. These devices require long-term follow-up and monitoring, and after implantation, regular follow-ups are conducted at specific intervals. These follow-ups provide crucial information about both the device and the patient, aiding in diagnosis and guiding treatment. These monitoring procedures, which are usually performed in a clinical setting, place a substantial burden on the healthcare system and its personnel. Remote follow-up and monitoring, as discussed in this article, has the potential to replace many in-clinic follow-up/monitoring procedures, meeting the device and patient monitoring needs without compromising safety. Thus, it can alleviate the burden on the healthcare system and its personnel in a cost-effective manner. This article aims to provide a comprehensive exploration of remote follow-up and monitoring for CIEDs.

**Keywords:** Cardiac implantable electronic device, follow-up, monitoring, remote

**ÖZET**

Kardiyak implante edilebilir elektronik cihaz implantasyonu, dünya genelinde geniş uygulamalara sahip, giderek artan sayıda hastada kullanılan bir tanı ve tedavi yöntemidir. Bu cihazlar uzun süreli takip/izleme cihazları olup, implantasyon sonrasında belirli aralıklarla düzenli takip yapılmaktadır. Bu takipler hem cihaz hem de cihazı taşıyan hasta hakkında önemli bilgiler sağlayarak tanı ve tedaviyi yönlendirir. Genellikle klinik ortamında gerçekleştirilen bu takipler, sağlık sistemine ve personeline önemli bir yük getirmektedir. Bu makalede ele alınan uzaktan takip/izleme, birçok klinik takip/izleme prosedürünü etkili bir şekilde yerine getirme potansiyeline sahiptir ve bunu yaparken güvenliği tehlikeye atmadan cihazın ve hastanın izleme ihtiyaçlarına cevap verebilir. Böylece, sağlık sistemi ve personeli üzerindeki yükü maliyet etkin bir şekilde hafifletme potansiyeline sahiptir. Bu makale, kardiyak implante edilebilir elektronik cihazlar için uzaktan takip/izleme konusunu kapsamlı bir şekilde ele almaktadır.

**Anahtar Kelimeler:** Kardiyak implante edilebilir elektronik cihaz, takip, izleme, uzaktan

**REVIEW**
DERLEME

**Serkan Çay**[1]
**Duygu Koçyiğit Burunkaya**[1]
**Serdar Bozyel**[2]

[1]*Division of Arrhythmia and Electrophysiology, Department of Cardiology, University of Health Sciences, Yuksek Ihtisas Cardiovascular Building, Ankara City Hospital, Ankara, Türkiye*
[2]*Department of Cardiology, University of Health Sciences, Derince Training and Research Hospital, Kocaeli, Türkiye*

**Corresponding author:**
Serkan Çay
✉ cayserkan@yahoo.com

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Cardiac implantable electronic device (CIED) implantations have exponentially increased worldwide due to various indications, including the therapy and monitoring of arrhythmias.[1] As a result, the increased volume of follow-ups places additional pressure on healthcare personnel and drains financial resources unnecessarily.[2] Additionally, about 25% of patients with a CIED do not visit a device clinic within the first year following implantation.[3] Moreover, older patients, disabled persons, and patients residing in rural areas distant from device clinics face difficulties in attending regular follow-ups. Patients with demanding social or professional lives may also prefer not to spend time on hospital visits. Lastly, the recent Coronavirus Disease 2019 (COVID-19) pandemic has shown us that we can and should address more social, business, and health-related issues without leaving home. Recent reports from continental societies suggest remote follow-up and monitoring of CIEDs as a primary strategy.[4-6]

### Definitions[4,7,8]

#### Device Interrogation

Data related to device settings and stored information is transmitted from the CIED to the device programmer. This data can be accessed directly from the programmer or transferred to a computer, mobile device, or dedicated web server/software.

**Remote Follow-up or Remote Interrogation**
Routine, scheduled, and automated remote CIED interrogations function similarly to in-person clinical follow-ups. Almost all device parameters, including automated capture threshold test values, can be obtained during a remote interrogation (RI) session. This process is also defined as "scheduled transmission."

**Remote Monitoring (RM)**
Device parameters are automatically and periodically transmitted according to a schedule, while unscheduled transmissions of device data occur in response to predefined alert conditions associated with the patient's clinical events. These events may include atrial and ventricular arrhythmias and the functionality of the device.

**Individual-Based Remote Monitoring**
An RM transmitter is allocated to a specific patient.

**Site-Based Remote Monitoring**
An RM transmitter is allocated to a specific site, especially in centers without onsite device interrogation capability, and can be used to gather device data from numerous individual patients.

**Unscheduled Interrogation/Transmission**
***- Patient-Initiated Follow-up or Interrogation***
The patient, in response to a perceived or actual clinical event, triggers an unscheduled interrogation of the device.

***- Alert-Initiated Interrogation***
Predefined programmed parameters, in response to a potentially actionable event, trigger an unscheduled interrogation of the device, which is capable of consistent and continuous connectivity.

**Remote Device Management**
This term generally refers to the combination of remote follow-up and remote monitoring in a single definition.

**Home Monitor**
A specifically designed remote telemetry device or a mobile application that communicates with the CIED to transmit encrypted data.

**Cardiac Implantable Electronic Device Ecosystem**
The ecosystem consists of implanted devices, clinical programmers, home monitors, personal mobile phones or tablets, and cloud-based systems and services with specific software and hardware from device manufacturers and other companies related to gathering patient data.

## ABBREVIATIONS

| | |
|---|---|
| AF | Atrial fibrillation |
| ATP | Antitachycardia pacing |
| CIED | Cardiac implantable electronic device |
| COVID-19 | Coronavirus Disease 2019 |
| CRT | Cardiac resynchronization therapy |
| ICDs | Implantable cardioverter-defibrillators |
| ILRs | Implantable loop recorders |
| RI | Remote Interrogation |
| RM | Remote Monitoring |
| RP | Remote programming |
| RV | Right ventricular |
| TRM | Time engaged in remote monitoring |
| TTM | Trans-telephonic monitoring |
| VF | Ventricular fibrillation |
| VT | Ventricular tachycardia |

**Remote Interrogation and *Remote Monitoring* Methods**
In the early 1970s, the initial instance of remotely assessing CIEDs was achieved through trans-telephonic monitoring (TTM) of permanent pacemakers. Device parameters, including sensing, pacing, battery longevity, and intracardiac electrograms, could be delivered via analog telephone landline transmission. Simultaneous communication between the patient and hospital staff was necessary during transmission (Figure 1A).

During the latter part of the 1990s, radiofrequency systems with wand-based technology and inductive capabilities, which allowed the real-time transfer of programmed, stored, and measured data from the patient's CIED to a receiver unit located at home, gained widespread popularity as a prominent method for remote interrogation of CIEDs. All data received from the CIED were then transferred from the transceiver to a central storage unit via either analog telephone landlines or cellular telephone networks. Stored and processed data could be evaluated by the responsible staff using a secure website in a scheduled manner (Figure 1B).

In the early 2000s, with advancements in technology, automatic wireless transmission of CIED data to a home transceiver periodically at set frequencies (daily, weekly, or monthly) was achieved. Additionally, unscheduled transmissions were conducted if certain alert conditions occurred, or a patient-initiated interrogation was started after a real or perceived clinical event. The transmitted data were relayed to a centralized storage unit, which could be either a physical or virtual database, using analog telephone landlines or cellular/wireless networks. The responsible staff could log on and access the transferred data via a secure, dedicated website (Figure 1B).

Currently, Bluetooth Low Energy technology permits secure automatic data transfer from the dedicated CIED to the patient's personal mobile phone or tablet. Consequently, RI and RM can be achieved regardless of time and place (Figure 1C).

Manufacturer-specific RM platforms vary in hardware, software, programming, and layout aspects. It is essential for members of the RM team to be knowledgeable about these manufacturer-specific differences. Therefore, the functionalities and constraints of various RM systems must be considered when determining the most suitable CIED system for an individual patient.

During remote monitoring, clinically actionable alarms can be marked as red (critical) and yellow (important). These alarms also vary depending on the type of device. For implantable cardioverter-defibrillators (ICDs) and pacemakers (PMs), multiple shock therapies should be identified as red alarms, along with ventricular fibrillation (VF) or ventricular tachycardia (VT) detection, therapy off, low battery voltage, out-of-range impedance values, and noise detection. Additionally, elective replacement time, out-of-range pacing threshold, single shock or antitachycardia pacing (ATP) therapy, atrial fibrillation (AF) or nonsustained ventricular tachycardia (NSVT) detection, increased right ventricular (RV) pacing, or decreased cardiac resynchronization therapy (CRT) pacing may require marking as yellow alarms. For implantable loop recorders (ILRs), clinical alarms may include a heart rate dropping below 30, complete

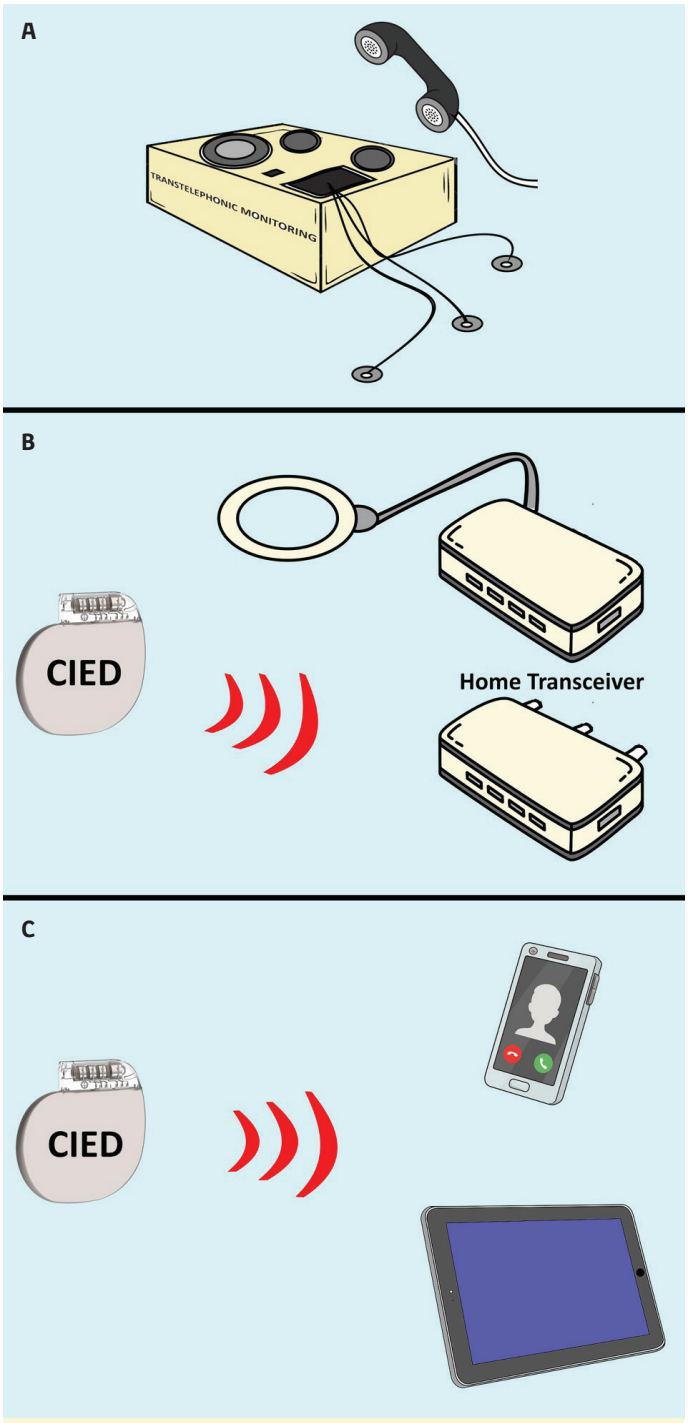


**Figure 1. Evolution of remote interrogation/monitoring methods (refer to the text for detailed information).**

**CIED, Cardiac Implantable Electronic Device.**

blocks with pauses longer than 6 seconds, tachycardias lasting more than 30 beats with a heart rate above 230, and AF episodes lasting more than 6 minutes in stroke patients, which can be identified as red alarms. In addition to these red alarms, low heart rates without complete blocks, pauses of 3-6 seconds, tachycardias between 180-230 beats per minute, and AF episodes longer than 6 minutes unrelated to stroke can be marked as yellow alarms.

Doctors should receive education on the principles of RM, covering the technology involved, the significance of RM in managing patients with CIEDs, and the clinical evidence supporting its use. This education can be provided through lectures, seminars, online modules, or educational materials from device manufacturers or professional organizations. Moreover, doctors should undergo hands-on training to utilize the specific RM systems associated with the CIEDs they implant. This training typically includes instruction on setting up RM equipment, interpreting RM data, troubleshooting technical issues, and responding appropriately to alerts or abnormal findings. Education should also emphasize clinical guidelines and protocols related to RM, covering indications for RM, the frequency of remote transmissions, and recommended actions in response to specific RM findings. Doctors may engage in case-based learning activities to apply their knowledge and skills in interpreting RM data within real patient scenarios. This could involve reviewing de-identified RM reports and discussing management strategies with colleagues or mentors. Given the evolving nature of RM technology and clinical evidence, doctors should receive ongoing continuing education to stay updated on advancements in RM practices, new guidelines, and best practices for optimizing patient care. Doctors may also opt to pursue certification or credentialing in RM through professional societies or device manufacturers. This process may entail completing specific training programs, demonstrating proficiency in RM skills, and passing examinations to obtain formal recognition of expertise in this area.

### Scientific Evidence

Various large-scale randomized trials and real-world evidence of RI and RM have been introduced in the medical literature. Almost all studies have shown equivalent or mostly better outcomes with RI and RM compared to the in-person evaluation of CIEDs.

### Randomized Trials

One of the earliest trials of RI for pacemakers is the PREFER (Pacemaker REmote Follow-up Evaluation and Review) study,[9] which had a prospective, randomly assigned, multi-center design. Nearly 900 patients were randomly assigned in a 2:1 ratio to either the remote interrogation (every 3 months; office visit at 12 months) using Medtronic CareLink™ or traditional office visits with Trans-Telephonic Monitoring (every 2 months; office visit at 6 and 12 months). The main objective of determining the average time for the initial diagnosis of a clinically actionable event was achieved sooner in the remote interrogation group compared to the conventional group (5.7 months vs. 7.7 months, $P < 0.0001$).

In the prospective, randomly assigned, multi-site TRUST (The Lumos-T Safely Reduces Routine Office Device Follow-Up) trial,[10] conducted in patients with an implantable cardioverter-defibrillator, 1,339 patients were randomized either to the Home Monitoring (HM) (Biotronik Home Monitoring®) group or the conventional follow-up group and were monitored for one year (HM, every quarter; scheduled office appointments at the 3-month and 15-month marks, along with regular office visits every 3 months). The Home Monitoring group exhibited a significantly higher completion rate for follow-ups compared to the conventional group, with rates of 93.5% and 88.7%, respectively ($P < 0.001$). Moreover, the HM group experienced

a 45% reduction in the overall number of conventional office appointments after 12 months ($P < 0.001$). The median time from the onset to the assessment of clinically significant arrhythmia episodes was notably shorter in the HM group (one day) compared to the conventional group (35.5 days) ($P < 0.001$). There were no differences between the two groups regarding adverse events and mortality.

Another randomized trial of RM of pacemakers is the COMPAS (COMPArative follow-up Schedule with home monitoring) trial,[11] in which 269 patients in both the HM (Biotronik Home Monitoring®) only and control groups were monitored for 18 months. At the end of the study period, no significant difference in major adverse events was found between the two groups (hazard ratio [HR] 0.90; 95% confidence interval [CI] 0.59-1.41; $P = 0.63$). The average number of interim follow-ups per patient-year was significantly lower in the Home Monitoring group than in the control group, showing a 56% reduction (95% CI -61 to -48; $P < 0.001$). The median time from the alert message to subsequent medical treatment was shorter in the Home Monitoring group (17 days) compared to the control group (139 days) (95% CI 49-184 days; $P < 0.001$).

In a similar prospective, randomized, multicenter study, the CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) study,[12] which included nearly 2,000 patients with defibrillator devices only, the median time between a clinically alert event and patient-specific clinical decision-making was shorter in the RM (Medtronic CareLink™) group (quarterly visits with additional in-office visits scheduled at 1-month and 15-month intervals) than in the in-office group (office visits at 1, 3, 6, 9, 12, and 15 months) (4.6 days vs. 22 days, $P < 0.001$, respectively). Additionally, data on healthcare utilization indicated a notable decrease in the average duration of hospitalization for cardiovascular reasons ($P = 0.002$).

In the non-inferiority ECOST (Effectiveness and Cost of ICDs Follow-up Schedule with Telecardiology) trial,[13] which evaluated the proportion of cases with at least one significant undesirable event, including all-cause mortality, cardiovascular occurrences, procedural aspects, and incidents related to CIEDs, 433 patients with a defibrillator device randomized in a 1:1 manner to the RM (Biotronik Home Monitoring®) and control groups were followed for two years. Subjects in the remote monitoring group had appointments within 1-3 months after device implantation, and subsequently at the 15$^{th}$ and 27$^{th}$ months during the follow-up period. Individuals in the control group had appointments within 1-3 months following device implantation, and subsequently at the 9$^{th}$, 15$^{th}$, 21$^{st}$, and 27$^{th}$ months during the follow-up period. Both intention-to-treat (HR 0.91; 95% CI 0.68-1.23; $P = 0.04$ for non-inferiority) and per-protocol (HR 0.90; 95% CI 0.67-1.21; $P = 0.04$ for non-inferiority) analyses showed no discernible distinction between the two groups regarding the incidence of any major adverse events. Furthermore, there was a 52% reduction in the incidence of inappropriate shocks ($P = 0.03$) and a 24% decrease in the frequency of follow-ups per patient per year ($P < 0.001$). In a sub-study of the ECOST trial[14], the implementation of remote management for patients with implantable defibrillators resulted in cost savings.

In patients with heart failure who have implantable defibrillators, the prospective, randomized, multicenter EVOLVO (Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators) study[15] randomized 200 patients to the RM (Medtronic CareLink™) and standard groups. The study demonstrated that patients followed up alternately every 4 months remotely and clinically had fewer primary endpoints of unscheduled visits to the emergency room or immediate in-office care appointments for issues related to heart failure, arrhythmias, or device-related incidents compared to patients followed up clinically every 4 months (incident-rate-ratio [IRR] 0.65; 95% CI 0.49-0.88; $P = 0.005$). The median duration from the device alert to the device check was 1.4 days in the remote monitoring group, compared to 24.8 days in the standard group ($P < 0.001$). Improvement in the quality of life over the study duration was more positive in the remote monitoring group compared to the standard group ($P = 0.026$). The use of remote management for heart failure patients with implantable defibrillators was shown to be cost-effective compared to the traditional approach of in-person evaluations (€291 vs. €381; $P = 0.01$).[16]

In the prospective, randomized, multicenter REFORM (Remote Follow-Up for ICD Therapy in Patients Meeting MADIT II Criteria) trial,[17] which included patients requiring implantable defibrillators as a preventive measure against sudden cardiac death, 155 patients were assigned to either quarterly or yearly (Biotronik Home Monitoring®) in-office visits after 3 months from randomization. The average overall count of planned and unplanned follow-up visits per patient-year after the 3-month assessment was greater in the quarterly in-office visit group (3.85) compared to the yearly in-office visit group (1.60) ($P < 0.001$). At the end of the study duration, quality-of-life assessments showed improvements in social functioning ($P = 0.019$) and mental health ($P = 0.021$).

In the prospective, randomized, multisite IN-TIME (INfluence of home moniToring on mortality and morbidity in heart failure patients with IMpaired lEft ventricular function) trial,[18] which evaluated the incremental benefit of automatic RM (Biotronik Home Monitoring®) for individuals with heart failure who had received a defibrillator implant, 664 patients were randomly assigned to the Home Monitoring and standard care groups. After a 2-year follow-up, the Kaplan-Meier estimate for all-cause mortality in the Home Monitoring group was 3.4%, compared to 8.7% in the standard group (HR 0.36; 95% CI 0.17-0.74; log-rank $P = 0.004$). Furthermore, the Kaplan-Meier estimate for cardiovascular mortality in the Home Monitoring group was 2.7%, contrasting with 6.8% in the standard group (HR 0.37; 95% CI 0.16-0.83; log-rank $P = 0.012$).

Recently, in a prospective, randomly assigned, multicenter European study (The European REMOTE-CIED study),[19] approximately 600 heart failure patients undergoing treatment with a defibrillator were randomized in a 1:1 ratio to the remote monitoring (Boston Scientific LATITUDE™ system) (followed every 6 months with in-clinic visits at 12 and 24 months) and an in-clinic follow-up group (followed every 3-6 months) and were monitored for two years. The study results showed that cardiac-related hospitalizations (HR 0.88; 95% CI 0.67-1.2; $P = 0.36$), all-cause mortality (HR 0.90; 95% CI 0.48-1.7; $P =$

0.73), cardiac-related mortality (HR 1.2; 95% CI 0.49-3.1; *P* = 0.65), and any CIED therapies (HR 0.65; 95% CI 0.39-1.1; *P* = 0.09) were not different between the two groups. Thus, remote monitoring demonstrated non-inferiority compared to traditional in-clinic visits concerning major clinical outcomes.

**Real-World Evidence**

The prospective ALTITUDE project was a remote follow-up network that incorporated implantable defibrillators compatible with the LATITUDE™ system manufactured by Boston Scientific Corporation. Nearly 70,000 patients remotely monitored at over 2,000 centers in the United States were evaluated in the ALTITUDE survival study.[20] Remote data transmissions occurred at an average frequency of four times per month, with in-person visits averaging twice per year. Nearly 125,000 patients with an implantable device not capable of networked transmissions constituted the standard care group. At five years, survival was significantly better in remotely monitored patients compared to standard care, with a relative risk reduction (RRR) of 40% in the total population and an RRR of 50% in the matched population.

The retrospective, observational MERLIN (Monitoring in Real-Time of Long-Term Outcomes in Patients with an Implantable Device) study[21] included nearly 270,000 patients with a CIED capable of automatic RM (Merlin.net™), including both defibrillators and pacemakers manufactured by St. Jude Medical. Weekly transmissions to the central unit were evaluated, and the proportion of total follow-up weeks with at least one transmission, referred to as the percentage of time engaged in remote monitoring (TRM), was described as RM adherence. Based on adherence, patients were divided into three categories: no RM (0% TRM, 53% of the population), low RM adherence (> 0% TRM and < 75% TRM, 22% of the population), and high RM adherence (≥ 75% TRM, 25% of the population). Over an average follow-up period of three years, patients with any RM had significantly lower mortality compared to those with no RM (mortality incidence rate ratio of 0.55). In Cox survival analyses, patients with high RM adherence demonstrated superior survival compared to those with low RM adherence and those with no RM (HR 1.32; 95% CI 1.27-1.36; HR 2.10; 95% CI 2.04-2.16, respectively). Additionally, survival was better in patients with low RM adherence compared to those with no RM adherence (HR 1.58; 95% CI 1.54-1.62). These differences remained significant regardless of device type.

In another European-based study, the Clinical Efficacy of remote monitoring in the Management of Heart Failure (EFFECT) study,[22] nearly 1,000 patients with an implantable defibrillator from 25 centers were divided into either an RM group or a standard in-clinic visit group and followed according to the usual protocols of the participating centers. All currently available CIED manufacturers' RM systems were included in the study. Mortality from any cause and cardiovascular hospitalizations were significantly lower in the RM group compared to the standard care group (HR 0.60; 95% CI 0.44-0.83). Additionally, RM was identified as an independent protective factor against the primary endpoint of all-cause death and cardiovascular hospitalizations.

**Guidelines**

Following multiple large-scale, prospective, randomized trials on RI and RM, the Heart Rhythm Society prepared an Expert Consensus Statement on RI and RM for CIEDs in 2015.[7] Research conducted since 2015 has consistently demonstrated the importance of RM and its potential beneficial impact on morbidity and mortality, further establishing RM as an essential component in the care of patients with CIEDs.[21,23-25] Consequently, a new guide was developed, resulting in the 2023 guidelines.[4] Some classes of recommendations and their levels of evidence are summarized in Table 1. Additionally, the 2021 European Society of Cardiology Guidelines on cardiac pacing and cardiac resynchronization therapy[5] provide valuable recommendations with evidence levels regarding RI and RM

**Table 1. Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS) Remote Monitoring Consensus Statement Recommendations[4]**

| Remote Interrogation (RI)/Remote Monitoring (RM) Recommendation | Class of Recommendation (COR) | Level of Evidence (LOE) |
|---|---|---|
| RM is recommended as an integral component of standard care. | I | A |
| RM is recommended for regular monitoring of lead function and battery status to maintain device integrity. | I | B-R |
| For patients with an implantable loop recorder (ILR), it is recommended to enroll them in a RM program before discharge, considering the daily availability of diagnostic data. | I | C-EO |
| Initiating RM prior to discharge or within two weeks of cardiac implantable electronic device (CIED) implantation can be beneficial. | IIa | B-NR |
| To prevent interruptions in RM, it is recommended to update patient information on the manufacturer's web-based platform whenever there are changes in the patient's clinical status. | I | C-EO |
| If there is a loss of connection, it is recommended for clinics to establish a procedure involving dedicated clinic staff to assist in reconnection. | I | C-EO |
| It is recommended to adopt a team-based organizational model with formal policies, procedures, and clearly defined roles and responsibilities for qualified staff to optimize all aspects of RM tasks. | I | B-NR |
| It is recommended for clinical providers who autonomously prescribe, interpret, and document RM to have appropriate education and/or certification. | I | C-EO |

**Table 1. Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/Asia Pacific Heart Rhythm Society (APHRS)/ Latin American Heart Rhythm Society (LAHRS) Remote Monitoring Consensus Statement Recommendations[4] (*continued*)**

| Remote Interrogation (RI)/Remote Monitoring (RM) Recommendation | Class of Recommendation (COR) | Level of Evidence (LOE) |
|---|---|---|
| When continuous connectivity is not available, it is recommended to conduct remote transmissions at intervals of at least every 3-12 months for pacemakers (PMs), every 3-6 months for implantable cardioverter-defibrillators (ICDs), and every 1-3 months for devices approaching elective replacement time. | I | C-EO |
| In centers lacking onsite device interrogation capability, it is reasonable to utilize site-based remote interrogation technology to enhance access to care. In centers equipped with onsite device interrogation capability, it is reasonable to utilize site-based remote interrogation technology to expedite care delivery. | IIa | C-EO |
| For a CIED component under a safety advisory, it is recommended to incorporate continuous connectivity into scheduled remote or in-person interrogation to facilitate early detection of actionable events. | I | B-R |
| For patients with CIEDs on RM with continuous connectivity, and in the absence of recent alerts or other cardiac comorbidities, it is reasonable to schedule in-person visits every 24 months. | IIa | B-R |
| It is recommended that clinic staff be knowledgeable about the specific differences among, and within, manufacturers' devices and their RM platforms to enhance patient care. | I | C-EO |
| It is recommended to tailor alert parameters according to clinical indications. | I | B-R |
| It is recommended that the ICD be configured to notify the clinic for all instances of ventricular shock therapies. | I | C-LD |
| It is reasonable to remotely monitor heart failure (HF) diagnostics to identify the occurrence or advancement of HF. | IIa | B-R |
| It is reasonable to program cardiac resynchronization therapy (CRT) to notify the clinic in the event of a low percentage of biventricular pacing. | IIa | C-LD |
| It is reasonable for the CIED to be programmed to notify the clinic upon the occurrence of the first episode, a prolonged episode, or a high burden of atrial arrhythmia. | IIa | C-LD |
| It is reasonable to program the CIED to alert the clinic for all instances of ventricular anti-tachycardia pacing therapies. | IIa | C-LD |
| It is reasonable to program the CIED to notify the clinic of an excessive percentage of right ventricular (RV) pacing. | IIa | C-EO |
| It is recommended for clinic staff to verify an actionable event transmission from the ILR by reviewing the electrograms to rule out misdiagnoses. | I | B-NR |
| It is recommended to customize programmed alerts of the ILR based on the clinical indication. | I | B-NR |
| When patients with ILRs experience frequent undersensing and/or oversensing while on RM, it is recommended to consider reprogramming. | I | B-NR |
| For unexplained syncope, it is recommended to stress to the patient the importance of performing a symptom marking or manual transmission from the ILR immediately following syncope to achieve a symptom-rhythm correlation. | I | B-NR |
| In patients with ILRs on RM for cryptogenic stroke, it is reasonable to adjust the sensitivity to enhance the detection of atrial fibrillation (AF). | IIa | B-NR |
| In patients with ILRs on RM with consistent connectivity, routine in-office visits are not necessary for routine patient care. | III | C-EO |
| It is recommended that for concerns related to critical device or lead function, high-priority alerts be programmed to promptly notify the clinic. | I | B-R |
| It is recommended to reprogram alert parameters to prevent non-actionable alerts. | I | C-EO |
| It is recommended to inform patients and their caregivers that automatic alerts transmitted by RM do not serve as a substitute for an emergency management system. | I | C-EO |
| It is reasonable for clinics to review and respond to high-priority alerts within one business day. | IIa | C-EO |
| It is reasonable to share the results of all remote device transmissions with patients, considering their preferences for content and mode of communication, as well as clinic workflows. | IIa | C-EO |
| It is recommended that patient instruction ought to be conveyed in straightforward terms, at a fundamental literacy level, and be tailored to accommodate patient communication preferences and educational requirements across the care continuum. Thorough patient education regarding RM is advised for patients, their families, and caregivers before the implantation of the device to facilitate collaborative decision-making concerning device selection. Patient education should commence prior to implantation and encompass the significance of maintaining continuous connectivity to enhance post-implant patient adherence and monitoring efficacy. | I | C-EO |

**Table 1. Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/Asia Pacific Heart Rhythm Society (APHRS)/ Latin American Heart Rhythm Society (LAHRS) Remote Monitoring Consensus Statement Recommendations[4] (*continued*)**

| Remote Interrogation (RI)/Remote Monitoring (RM) Recommendation | Class of Recommendation (COR) | Level of Evidence (LOE) |
|---|---|---|
| Manufacturers ought to furnish clinic personnel with sufficient training, instruction, and technical assistance to enhance individual patient connectivity. The manufacturer should supply an RM system that is dependable, secure, precise, and aligns with patient requirements. Manufacturers should engage key stakeholders in the design and advancement of RM technologies. Manufacturers should ensure swift notification of disconnections to both the clinic and the patient to reinstate connectivity. | I | C-EO |
| Manufacturers are responsible for reaching out to managing clinics with comprehensive safety advisories and aiding in the identification of affected patients both promptly and regularly. Additionally, manufacturers should offer guidance to clinics regarding optimal alert configurations to effectively address the safety advisory. | I | C-EO |
| It is recommended for manufacturers to allocate sufficient resources, including personnel as needed, to guarantee enrollment and connectivity to RM platforms before discharge or within two weeks of implantation. Additionally, it is recommended that manufacturer representatives furnish clinic staff with comprehensive training to correctly program remote alerts tailored to the clinical indication, thereby minimizing inappropriate alerts and the necessity for subsequent reprogramming. | I | C-EO |
| Utilizing third-party resources to mitigate RM workload for staff is reasonable. It is also reasonable to inform patients about the utilization of third-party resources to enhance patient care. | IIa | C-EO |
| Health systems should identify local barriers and develop strategies to optimize the successful implementation of RM on a global scale. | I | C-EO |
| Healthcare payers are recommended to implement sufficient reimbursement for RM customized to regional healthcare system care patterns. | I | B-NR |

AF, Atrial Fibrillation; APHRS, Asia Pacific Heart Rhythm Society; CIED, Cardiac Implantable Electronic Device; COR, Class of Recommendation; CRT, Cardiac Resynchronization Therapy; EHRA, European Heart Rhythm Association; HF, Heart Failure; HRS, Heart Rhythm Society; ICD, Implantable Cardioverter-Defibrillator; ILR, Implantable Loop Recorder; IPE, In-Person Evaluation; LAHRS, Latin American Heart Rhythm Society; LOE, Level of Evidence; PM, Pacemaker; RI, Remote Interrogation; RM, Remote Monitoring; RV, Right Ventricular.

**Table 2. ESC Remote Monitoring Recommendations[5]**

| RI/RM Recommendation | COR | LOE |
|---|---|---|
| Remote CIED management is recommended to reduce the number of in-office follow-ups for individuals with pacemakers who have difficulty attending in-office visits (e.g., due to reduced mobility, other commitments, or by patient preference). | I | A |
| RM is recommended when a CIED component has been recalled or is under advisory, to enable early detection of actionable events in patients, particularly those at higher risk (e.g., in cases of pacemaker dependency). | I | C |
| Routine in-office follow-up for single- and dual-chamber pacemakers may be spaced up to 24 months for individuals on remote CIED management. | IIa | A |
| Remote CIED management of pacemakers should be considered to enable earlier detection of clinical issues (e.g., arrhythmias) or technical problems (e.g., lead failure or battery depletion). | IIa | B |

CIED, Cardiac Implantable Electronic Device; COR, Class of Recommendation; ESC, European Society of Cardiology; LOE, Level of Evidence; RI, Remote Interrogation; RM, Remote Monitoring.

(Table 2). It is recommended that all CIEDs undergo in-office checks within 72 hours and between 2 to 12 weeks after implantation. During follow-up, along with RM, RI every 3-6 months, in-office visits every 12 months, and unscheduled in-office visits if an alert condition occurs should be considered. For single- and dual-chamber pacemakers, in-person office visits can be extended to every 18-24 months.

### Remote Device Programming

In healthcare institutions without on-site CIED specialist staff, a standard programmer connected to the patient can be securely linked to the internet using a remote support unit. Through dedicated software, a CIED specialist can securely connect their personal computer or tablet to the programmer. This allows the specialist to view the programmer's full screen remotely and utilize the programming features of the device according to the patient's needs. During this RI session, both visual and verbal communication should be maintained between the CIED specialist and the hospital staff caring for the patient.[26]

Imaging examinations, especially magnetic resonance imaging (MRI) scans, can be problematic for individuals with a CIED. Before an MRI scan, the MRI staff place the wand of a standard programmer equipped with remote-control software and

connected to the internet over the device. A CIED specialist, often from the device manufacturer, accesses remote software to view the programmer's screen and set the device to MRI-safe mode. After the MRI scan, the device is reprogrammed to its initial settings.[27]

Remote programming (RP) is anticipated to reduce unnecessary utilization of healthcare resources and manpower. This reduction will, in turn, lower healthcare costs by requiring a smaller workforce for device programming and eliminating travel expenses associated with physical presence at the location. RP of CIEDs can be especially beneficial in rural areas where healthcare access is limited. Additionally, during pandemics such as COVID-19, RP helps reduce interregional transportation, thereby minimizing personnel exposure to infections. However, several challenges are associated with RP of CIEDs, including the need for a stable connection with the device from a remote location, cybersecurity concerns, and potential transmission delays.

### Questions Awaiting Answers

As in many countries, reimbursement problems exist regarding RI and RM in our country. Although RI/RM systems are secure, there are theoretical risks of cyber-attack and cybersecurity vulnerabilities. How will the increased implantation of CIEDs, along with the resulting rise in RI/RM and big data, be analyzed? What responsibilities do governments, social security institutions, device companies, clinics, doctors, allied health staff, subcontractors, and patients hold in RI/RM? Does the personal data protection law pose a concern? What should be the healthcare worker's response time to CIED RI/RM? Is patient privacy adequately protected? Are there legal regulations for data storage, protection, and destruction? Is RI and RM truly cost-effective? Can RI/RM systems integrate with artificial intelligence and machine learning technologies?[28] These issues appear to be solvable.

### Conclusion

Currently, there is insufficient legal regulation in Türkiye for remote cardiac implantable electronic device monitoring. According to the Personal Data Protection Law, the collection, storage, and sharing of patients' personal information require consent. Inadequate infrastructure, including unreliable internet connectivity, incompatible device systems, and disparities in healthcare access and socioeconomic factors, may pose challenges in some regions of Türkiye, particularly in rural or underserved areas. Additionally, it remains unclear who will access the substantial amount of data obtained through remote monitoring, who will be responsible for acting on this data, and when action should be taken. Furthermore, there is currently no reimbursement for the hardware and software used in remote monitoring, with expenses expected to be covered by the patient. Although some centers have implemented practices to reduce contact between patients and healthcare personnel during CIED follow-ups through individual efforts, there is no systematic remote CIED monitoring program in place. Lastly, despite the recent rise in digital literacy, the level of digital literacy in our country, especially among those undergoing CIED implantation, remains insufficient.

Addressing these challenges will require collaboration among healthcare stakeholders, including policymakers, healthcare providers, and device manufacturers. Given these factors, comprehensive legal regulations should be established based on exemplary practices worldwide. Healthcare personnel (as certified task-based remote monitoring teams), patients (as remote monitoring participants), and their families should receive education on device use, optimal remote monitoring practices, device programming, and troubleshooting. Furthermore, dedicated time is necessary to support the workload associated with remote monitoring. This approach would not only alleviate the burden of scheduled and unscheduled follow-ups on the healthcare system and personnel but also improve the quality of device clinics, enabling more effective patient care. Additionally, it would support research publication, contributing to the scientific literature based on the data obtained.

To engage patients in the CIED remote monitoring program, various strategies can be employed. For patients who are interested in and understand CIED remote monitoring, presenting statistics, evidence, or factual comparisons may be effective. However, for patients who are less interested or have difficulty understanding, appealing to emotions, values, or social norms may be more effective. Establishing a healthy relationship and building trust is crucial, and it may be necessary to explain the topic in simple terms using visual aids such as pictures and videos.

Knowing they are being monitored through CIED remote monitoring, whether continuously or intermittently, will enhance patients' sense of security and trust. Reducing face-to-face appointments and associated travel and missed work costs will help minimize both time and financial losses. Furthermore, promptly identifying any abnormalities within the CIED system without compromising safety will enhance patient care, particularly for conditions such as device status or therapies (red and yellow alerts representing high-priority alerts), heart failure, and atrial fibrillation.

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