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# *Clinical* EVIDENCE

## Adherence to remote monitoring guidelines for CIEDs in clinical practice

*Current clinical practice versus remote monitoring recommendations for cardiovascular implantable electronic devices: A real-world analysis from a remote monitoring database (Bertini et al.)* [1]

## Real-time Remote Technical Support for CIED Follow-up

*Real-time Technical Support Using a Remote Technology During Cardiac Implantable Electronic Device Follow-up: A Preliminary Multicenter Experience in Clinical Practice (Bianchi et al.)* [2]

## Insights from the PRAETORIAN Trial

*Inappropriate Therapy and Shock Rates Between the Subcutaneous and Transvenous Implantable Cardiac Defibrillator: A Secondary Analysis of the PRAETORIAN Trial (Nordkamp et al.)* [3]

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## Summary

This edition of Clinical Evidence offers an overview of the adherence to recommendations for remote monitoring (RM) in CIEDs follow-up and innovations that have been developed to assist physicians in enhancing the use of this technology, with a focus on Heart Connect preliminary experience. This issue also explores the latest findings from a sub-analysis of the PRAETORIAN study.

An analysis[1] of data from the LATITUDE™ remote monitoring system showed that while remote monitoring (RM) use is growing, several aspects are still critical for effective and optimal use in clinical practice with high volumes of scheduled and in-office visits. The use of Heart Connect, a real-time remote technical support service, has proven[2] to be feasible, effective, and well-accepted for providing prompt technical support to physicians during in-person CIED follow-up.
The sub-analysis[3] of the PRAETORIAN study demonstrated comparable rates of inappropriate therapies between S-ICD and TV-ICD in the conventional ICD population. However, these results should be reinterpreted in light of the advancements in S-ICD technology introduced in recent years.

# Adherence to remote monitoring guidelines for CIEDs in clinical practice

## Are we fully leveraging the remote monitoring of CIEDs according to the recommendations?

Recently the *Expert Consensus Statement on the Practical Management of Remote Device Clinic*[4] has been published on **Europace Journal** to provide evidence-based recommendations for managing patients with CIEDs.

To evaluate clinical practice in relation to these recommendations, an analysis of data from LATITUDE™ Monitoring system of all CIEDs (pacemaker, ICD, CRT, S-ICD) followed at 26 Italian centres was conducted by Prof. Bertini *et al*.[1]

Data from **6.553 CIED patients** followed in LATITUDE between 2010 and 2023 were analysed for a median monitoring period of 40 [23–67] months.

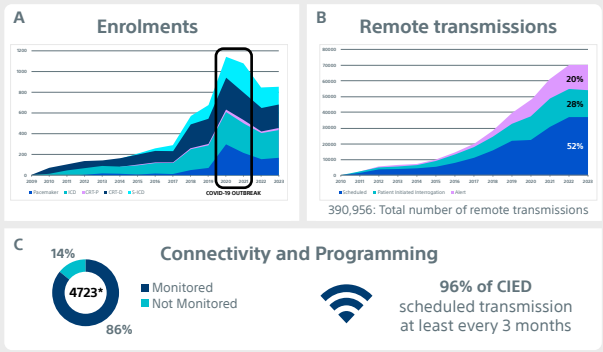


**Figure 1:** (A) Trend of enrolments in the RM system; (B) Volume of remote transmission over the monitoring period; (C) Connectivity and Scheduled transmission

## Results and implications

In the last years, the enrolments in remote monitoring (RM) system is increasing, especially during the COVID-19 outbreak (2020-2021) to limit face-to-face interactions, resulting in a peak in enrolments (Figure 1A).

At the same time, the burden of remote transmissions has increased significantly (Figure 1B).

The analysis highlighted **critical aspects for optimising CIED remote monitoring in clinical practice**, while several validated tools are available to support hospitals in addressing the identified gaps in the most critical areas.

### Enrolments

*"In patients with a CIED, it can be beneficial to initiate RM prior to discharge or within 2 weeks of CIED implantation."*

Only **73% of devices** were activated within two weeks

Median time from implant to RM enrolment was 11 [3–43] days

**Remote training** delivered to patients by the remote technical support team has been previously shown to be effective[5]

### Connectivity

*"Continuous connectivity may facilitate the alert-based RM and extends remote patient management beyond periodic calendar-based follow-up."*

**14%** of patients were NOT MONITORED at the time of data analysis with no significant differences among CIED types

**Dedicated app** has proven effective to allow patients to maintain a continuous connectivity during follow-up[6]

### Programming

*"[Alert-based RM] has the potential to replace structured intermittent device follow-up.*

*Individualising RM alerts... can improve clinic efficacy."*

Scheduled transmissions were programmed every 3 months in 96% of patients.

Lack of settings optimisation led to an **excess in workload of up to 83%***

**Personalised coaching** to support physicians in optimal scheduling and device programming to meet the clinical indications

### In-person visits

*"[Alert-based RM] could minimise low-value effort, optimise clinic visits for actionable events and decrease health care costs."*

Fairly high frequency of in-office visits with a median of 1.4 visit per patient per year

**Real-time support** for more efficient and prompt management has proven to facilitate in-person visits due to actionable events[2]

*"There is a need for improving adherence to RM recommendations for a more effective, efficient, and sustainable use of the technology.*

*Centres seem to be far from applying a primarily alert-based strategy, which could allow them to reduce the significant burden of non-actionable remote and in-office interrogations."*

**In terms of staff time required*

## Preliminary experience of real-time remote technical support during CIEDs follow-up

As well detailed previously, current recommendations emphasise the need of an alert-based approach that may increase the complexity of in-office visits, as emergencies or technical issues often require advanced expertise and longer consultation times.

Furthermore, follow-up activities place a significant burden on healthcare resources, as cardiologist, nurses, internal technicians and company technical personnel, as industry-employed allied professionals (IEAPs).

The **Heart Connect**™ application recently proposed by Boston Scientific's a **data-sharing system designed to facilitate online real-time meetings between physicians and IEAPs**, allowing them to remotely access and share the display of the CIED Programmer (Figure 2).

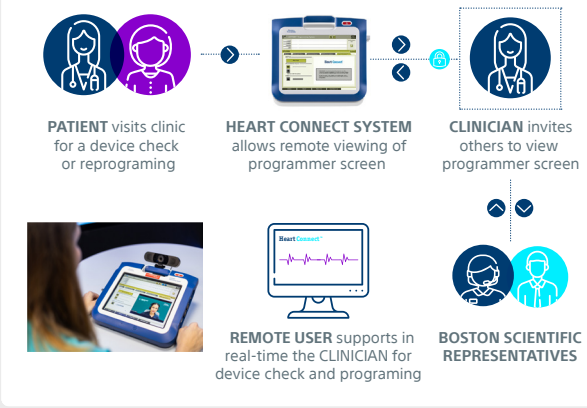


**Figure 2:** Heart Connect™ remote support during CIEDs follow-up

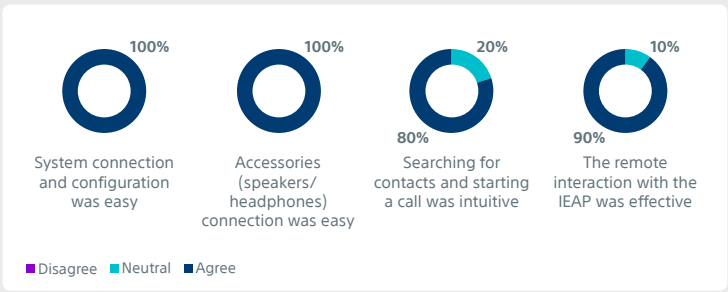


**Figure 3:** Ease of use and operators feedback

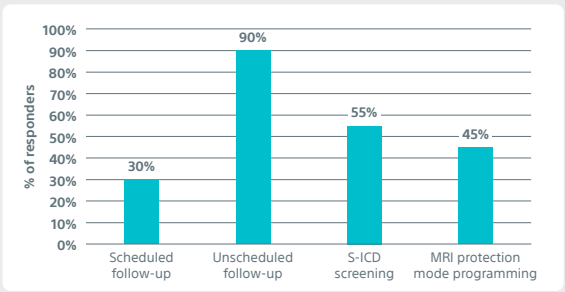


**Figure 4:** Preferred use in clinical practice

## Results

A survey was conducted among the first 6 early-adopter centres in Italy utilising Heart Connect support to evaluate its application in clinical practice, focusing on feasibility, effectiveness, ease of use, efficiency and operator's feedback.

- 20 operators trained by remote IEAPs (RhythmCARE™ team): after a short training 80% of operators were completely confident with Heart Connect.
- A total of 208 visits were attempted and **97% completed successfully only with Heart Connect support.**
- The **quality of the connection**, sound and video were rated **good or excellent in more than 95% of sessions.**
- The most preferred use of Heart Connect in clinical practice is for unscheduled follow-up visits (Figure 4), which are often the most actionable and may require immediate intervention as well as advanced technical skills.

**90%** Remote support can **effectively replace the on-site IEAP support for** scheduled and unscheduled visits

**95%** Real-time on-demand remote support **facilitates follow-up management** in the centre

**60%** The remote support allows to **decrease the duration of visits** (+30% declared no changes in duration)

**80%** **Fully satisfied with the use of Heart Connect**

Heart Connect has been established as a viable alternative to traditional on-site IEAP support for both scheduled and unscheduled follow-up visits involving various types of CIEDs.

## Are Inappropriate Therapies Truly Comparable Between T-ICD and S-ICD?

The PRAETORIAN trial[7] is the first randomised controlled trial comparing the effectiveness and safety of the S-ICD and TV-ICD in a conventional ICD population, with prespecified ICD programming, and showed noninferiority of the S-ICD with regard to the combined primary end point of inappropriate shocks (IAS) and complications.

This secondary analysis[3] offers insights into the occurrence, causes, and predictors, of inappropriate therapies – both ATP and shocks – in both groups.

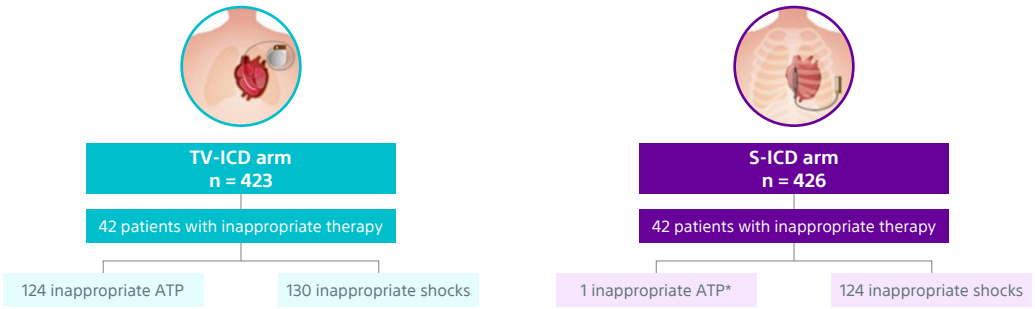


**Figure 5:** Overview of inappropriate therapies

**Occurred in 1 patient who crossed over to a TV-ICD*

## Results

Patients were randomised to receive an S-ICD (n = 426) or TV-ICD (n = 423; Figure 5).

During a median follow-up of 49.1 months:

- **There was no significant difference in patients** (n = 42) **experiencing inappropriate therapy** between both groups (p = 0.14).
- Inappropriate episodes were most frequently **caused by supraventricular tachycardias** in the **TV-ICD** group (n = 83/89) versus **cardiac oversensing** in the **S-ICD** group (n = 40/81).
- In the TV-ICD group, a baseline heart rate > 80, a history of atrial fibrillation and smoking were **independent predictors for inappropriate therapy**. QRS duration was not an independent predictor for inappropriate therapy in the S-ICD group, but it was an independent predictor for inappropriate therapy caused by cardiac oversensing.
- Post-IAS interventions significantly reduced **IAS recurrence** in both groups (p = 0.046).

Some factors should be considered when interpreting the study's results in the context of modern device therapy:

- The PRAETORIAN trial, initiated in 2011, used a **cut-off rate of 182 bpm**, while current programming typically uses 200 bpm[8], potentially reducing IAS.
- Limited electrogram availability, especially in the TV-ICD group due to storage constraints, may have led to underreporting of inappropriate therapies especially in the TV-ICD group.
- Most S-ICD patients (88.7%) **received first-generation devices without the SMART Pass filte**r, which could have lowered IAS rates with newer devices. Indeed, SMART Pass was not available in 70.7% of patients at the time of IAS in the S-ICD group.

**96.2%**
Screening success rate

The S-ICD screening ECGs performed prior to implantation were not collected in this study, preventing an analysis of whether specific characteristics on these screening could predict IAS in the S-ICD group.

However, a recent French study by De Guillebon[9] demonstrated a very high modern-era screening passing rate on first attempt (96.2%) showing that:

- **Most patients are suitable for an S-ICD.**
- There is **no association between the number of vectors** validated during screening **and the occurrence of IAS** during follow-up.

This sub-analysis of the PRAETORIAN Trial found no significant difference in inappropriate therapy or IAS rates between S-ICD and TV-ICD in a conventional ICD population. However, the results require careful re-interpretation as outlined in the paper.

# "Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices"[10]

*NICE guidance 2024*

In October 2024, NICE, the National Institute for Health and Care Excellence, which provides evidence-based guidance to improve healthcare quality and efficiency in the United Kingdom, issued updated recommendations[10] on the use of heart failure (HF) algorithms for remote monitoring in patients with cardiac implantable electronic devices (CIEDs).

The Diagnostics Advisory Committee performed a systematic review of all available literature to determine the clinical and cost effectiveness of four remote monitoring algorithms* for detecting HF.

The HeartLogic™ algorithm has been recommended as an option for algorithm-based remote monitoring in people with CIEDs.

**Breaking News**

NICE recommend the use of HeartLogic in patients with heart failure as part of a specialist multidisciplinary service

## What the key points?

### Predictive power

**HeartLogic predicts heart failure events, enabling prompt intervention through alert notification**

*"HeartLogic showed sensitivity ranging from 70% to 100%, and specificity ranging from 61% to 93%. False positives and unexplained alert rates were generally low."*[10]

### Cost-effectiveness

**HeartLogic is a cost-effective tool, generating savings for National Health Service (NHS)**

*"...a 72% lower rate of hospitalisations in the intervention [HeartLogic] group....These inputs resulted in the technology being dominant (less costly and more effective than standard care)."*[10]

### Improved outcome

**HeartLogic can reduce HF events and unnecessary in-person visit by using alerts notification and remote assessment**

*"Evidence suggests that using the HeartLogic algorithm [...], provides statistically significant reductions in: hospitalisations, rate of HF events, length of hospital stay, emergency or urgent care visits."*[10]

*The committee noted that the evidence available for **HeartLogic** [...] suggests that it **can accurately detect the signs of worsening heart failure** that could lead to hospitalisation or an unscheduled clinic event. The evidence also suggests that **HeartLogic [...] can reduce the number of heart failure events** compared with conventional remote monitoring.*

*HeartLogic (Boston Scientific), CoreVue (Abbott Medical), HeartInsight (Biotronik), TriageHF (Medtronic)

## Key Messages

- **Adherence to remote monitoring guidelines for CIEDs in clinical practice:** The use of remote monitoring is growing in clinical practice, however, there are critical issues to ensuring its effectiveness, efficiency, and sustainability in real-life. To address these challenges and improve the use of remote monitoring, several innovative solutions have been introduced to support physicians[1].
- **Real-time Remote Technical Support for CIED Follow-up:** Remote support using HeartConnect™ during CIED follow-up proved feasible, effective, and well-accepted by operators, offering a viable alternative to on-site IEAPs support for both scheduled and unscheduled follow-up visits[2].
- **Insights from the PRAETORIAN Trial:** This multicenter randomised study found no significant difference in inappropriate therapy rates and IAS rates between the S-ICD and TV-ICD in a conventional ICD population[3].

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## CAUTION:

The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device, or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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