New Thinking on Remote Management of CRT Non-responders

Anoop K. Gupta
MD, DM, DNB, FACC, FSCAI, FESC.
Interventional Cardiologist and Cardiac Electrophysiologist,
Ahmedabad. Gujarat. India

KHRS 2023: The 15th Annual Scientific session of the KHRS. 23rd and 24th June, 2023. Seoul.

Disclosures

- CRM proctor
  - Abbott
  - Medtronic
  - Boston Scientific
  - Biotronik

- Proctor for J& J (Webster Cordis)
  - Promotion and new center activations

Preface

- Remote monitoring (RM) of patients with cardiac implantable electronic devices received Class 1 recommendation in 2015.

- Adoption varies by device type; complex devices are perceived to gain most.

- Cardiac resynchronization therapy (CRT) is the most complex cardiac implantable electronic device, and "non-responders" (CRT- NR) have one of the poorest prognosis among heart failure patients.

- RM enables early detection of potential precipitants of decompensation (e.g. atrial fibrillation, loss of % CRT pacing, volume changes), and thereby facilitates early pre-emptive intervention to improve patient outcomes.

Key Points

- Remote monitoring of CIED is recommended as standard of care (Digital health technologies).

- Cardiac resynchronization therapy (CRT) implanted in the United States had remote monitoring implemented in approximately 60%, contrasting with only 6% in Asia. Following diagnosis of nonresponse, there was no change in remote monitoring utilization.

- Barriers to remote monitoring need to be identified to improve patient care. This is important to this high-risk group of patients and to adoption of digital health technologies in general.

Patient Profile

Male, 40 Yrs.

- Diabetes mellitus
- Non-ischemic dilated cardiomyopathy
- NYHA class II, sinus rhythm, LBBB, QRS: 180ms
- Severe LV systolic dysfunction (EF: 30%)

Successful CRT-D implantation GALLANT™ HF with Bluetooth Remote Monitoring.

Post Implant Report

FastPath™ Summary

Page 1 of 1

Battery

~ERI > 5 yrs

Implant Date: 4 Sep 2020

Last Max Charge 8.1 sec (4 Sep 2020)
Battery Current 23 uA
Remaining Capacity to ERI >95%

Longevity estimate is available after 24 hours of patient history is collected

Test Results 4 Sep 2020 — Automatic

	Capture	Sense	Lead Impedance
A	Not Performed No previous results	Not Performed >5.0mV (Bi)	Not Performed 490 Ω (Bi)
RV	Not Performed 0.75V @ 0.5ms (Bi)	Not Performed 8.3mV (RV Bi)	Not Performed 530 Ω (Bi)
LV	Not Performed 1.0V @ 0.5ms (M2-M3)		Not Performed 990 Ω (M2-M3)
HV			Not Performed 87 Ω (RV to Can)

Capture & Sense	A	RV	LV	LV2
Cap Confirm	Off	Off	Off	
Pulse Amplitude	2.5 V	2.5 V	4.0 V	
Pulse Width	0.5 ms	0.5 ms	0.5 ms	
AutoSense	On	On		
Sensitivity	Auto A	Auto A		

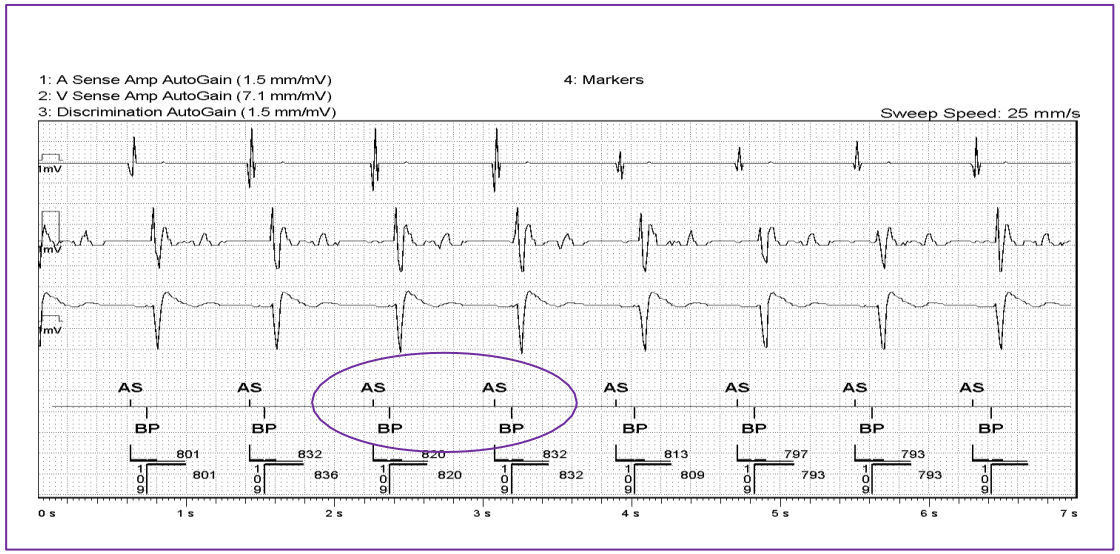
Diagnostics Summary Since 4 Sep 2020

AP	0 %
BP	>99 %
AMS Episodes	0
Mode Switch	0%
AT/AF Burden	0%

VT/VF Episodes: 0 Since 4 Sep 2020

	VT	VF
Episodes	0	0
ATP Delivered	0	0
Shocks Delivered	0	0

SVT Episodes: 0
Non-sustained Episodes: 0



- Post Implant Parameters were tested.
- Patient was discharged with ongoing Bi-V pacing

Transmission Findings

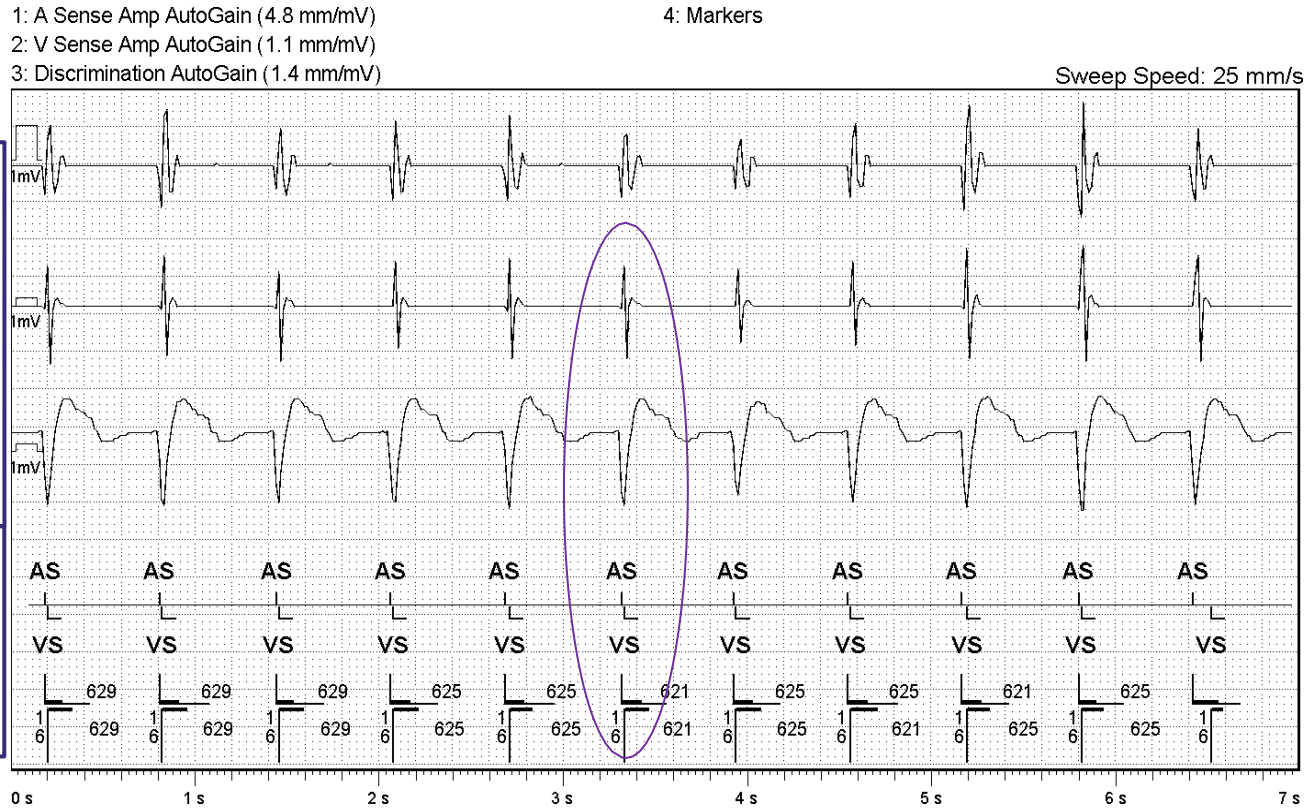
- FastPath™ Summary showed 'No Alerts'

30 Sec Live EGMs feature enabled in our Merlin Remote Monitoring showed No-Ongoing CRT Pacing.

FastPath™ Summary Page 1 of 1

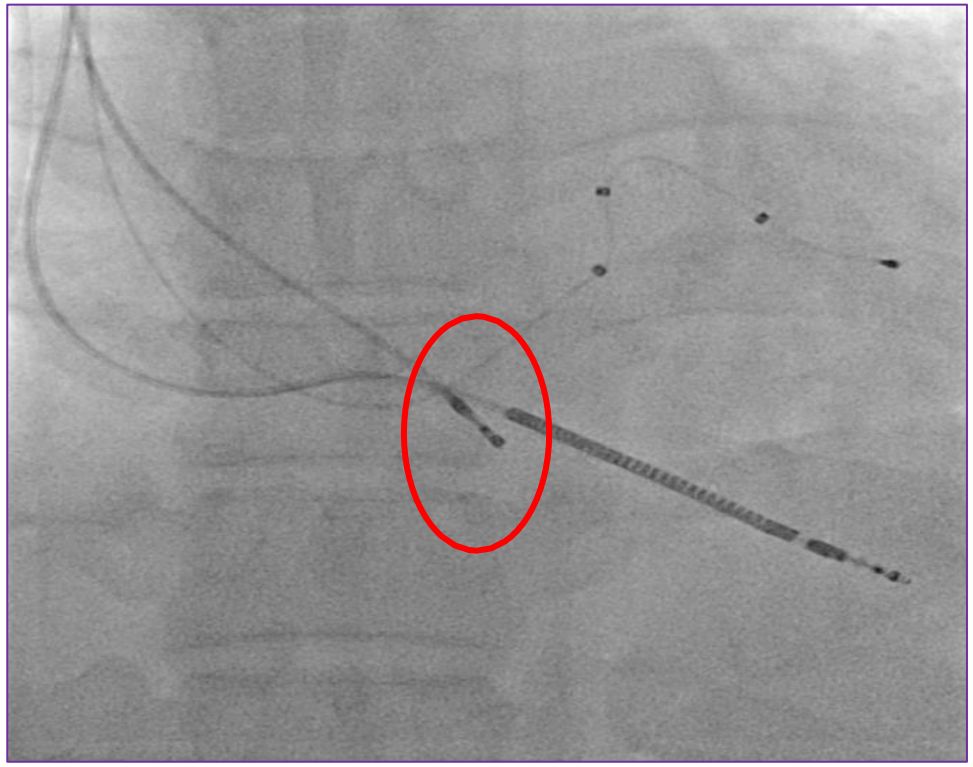
Battery	Implant Date:	4 Sep 2020
~ERI > 5 yrs	Last Max Charge	8.1 sec (4 Sep 2020)
	Battery Current	19 uA
	Remaining Capacity to ERI	>95%

No Alerts

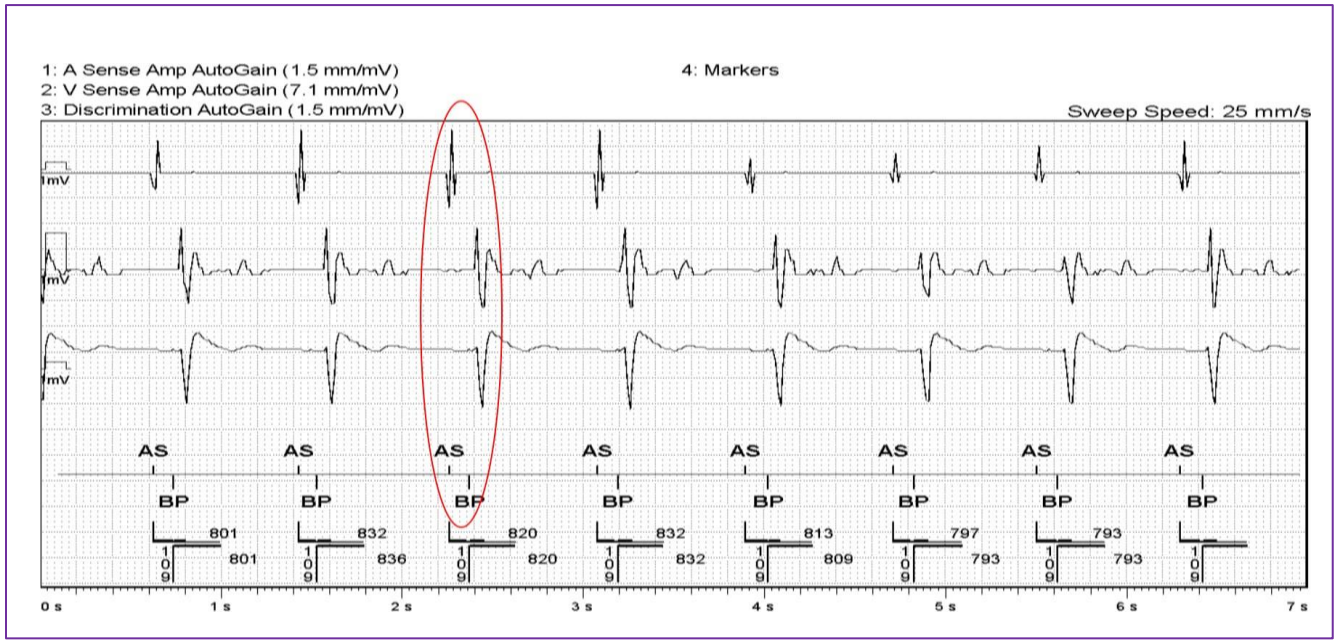


Follow- up Visit Findings

Fluoro Scanning confirmed Atrial Lead Dislodgment



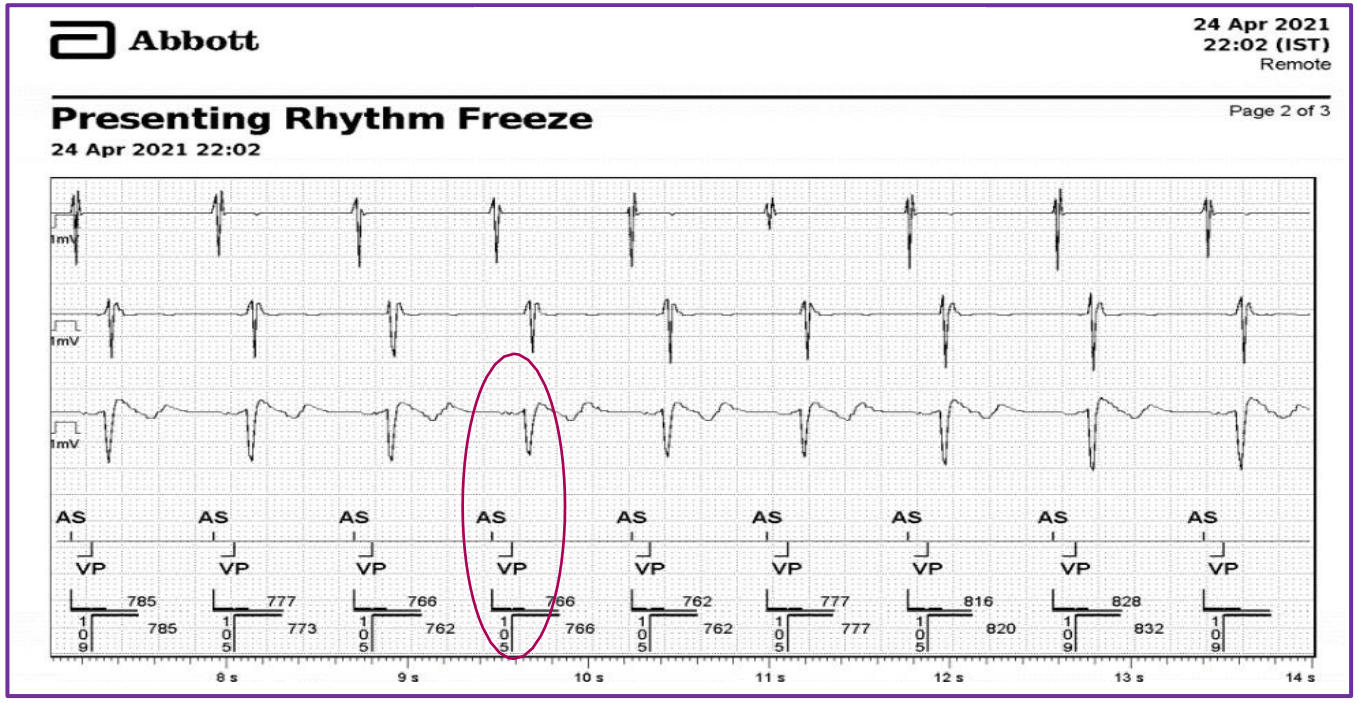
- The lead was re-positioned.
- Live EGM shows Ongoing CRT Pacing.



Latest Transmission of the Patient

Latest reports of the patient >99% LV only pacing.

Feature available with Next Generation Gallant CRT Devices for achieving fusion based pacing.



Abbott

24 Apr 2021
22:02 (IST)
Remote

Presenting Rhythm Freeze

Page 2 of 3

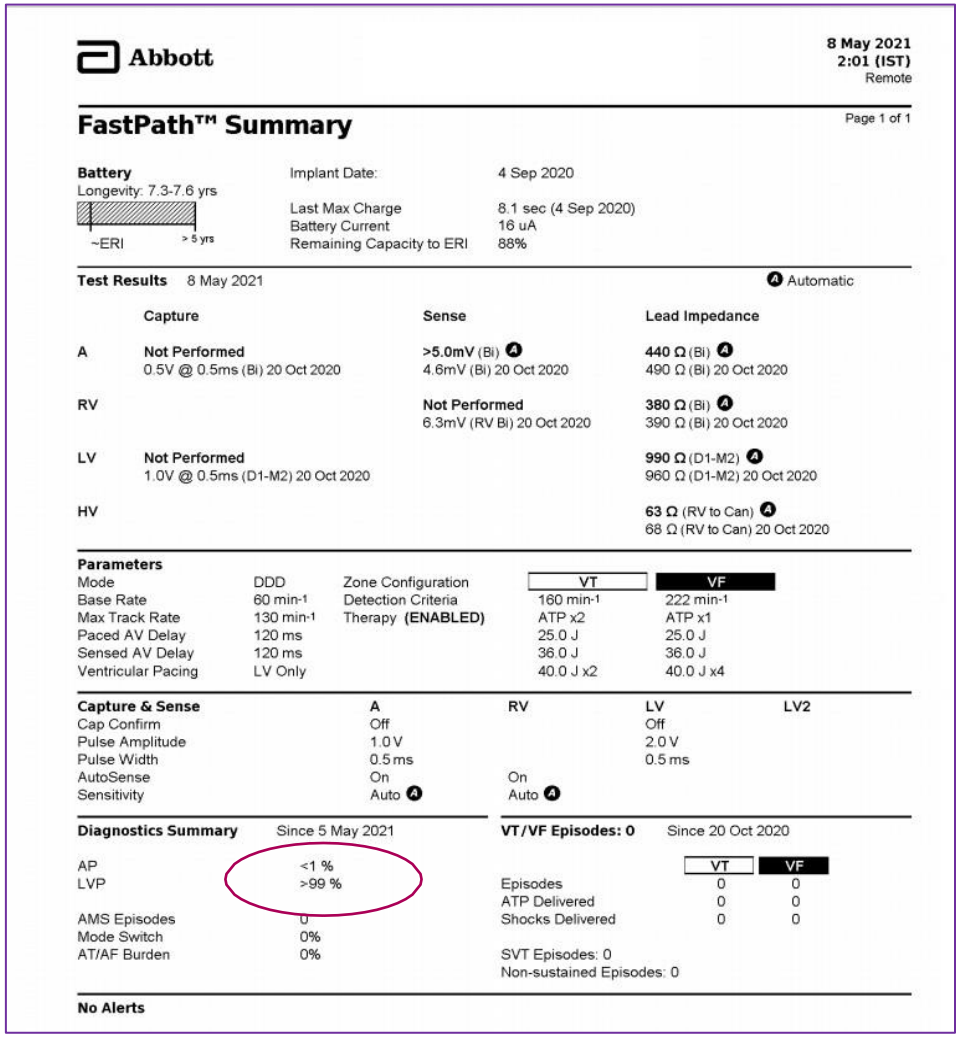
24 Apr 2021 22:02

1mV
1mV
1mV

AS AS AS AS AS AS AS AS AS
VP VP VP VP VP VP VP VP VP

785 777 766 766 762 777 816 828
785 773 762 766 762 777 820 832

8 s 9 s 10 s 11 s 12 s 13 s 14 s



Abbott

8 May 2021
2:01 (IST)
Remote

FastPath™ Summary

Page 1 of 1

Battery
Longevity: 7.3-7.6 yrs
~ERI > 5 yrs

Implant Date: 4 Sep 2020
Last Max Charge 8.1 sec (4 Sep 2020)
Battery Current 16 uA
Remaining Capacity to ERI 88%

Test Results 8 May 2021 (A) Automatic

	Capture	Sense	Lead Impedance
A	**Not Performed** 0.5V @ 0.5ms (Bi) 20 Oct 2020	**>5.0mV** (Bi) (A) 4.6mV (Bi) 20 Oct 2020	**440 Ω** (Bi) (A) 490 Ω (Bi) 20 Oct 2020
RV		**Not Performed** 6.3mV (RV Bi) 20 Oct 2020	**380 Ω** (Bi) (A) 390 Ω (Bi) 20 Oct 2020
LV	**Not Performed** 1.0V @ 0.5ms (D1-M2) 20 Oct 2020		**990 Ω** (D1-M2) (A) 960 Ω (D1-M2) 20 Oct 2020
HV			**63 Ω** (RV to Can) (A) 68 Ω (RV to Can) 20 Oct 2020

Parameters

			VT	VF
Mode	DDD	Zone Configuration		
Base Rate	60 min-1	Detection Criteria	160 min-1	222 min-1
Max Track Rate	130 min-1	Therapy **(ENABLED)**	ATP x2	ATP x1
Paced AV Delay	120 ms		25.0 J	25.0 J
Sensed AV Delay	120 ms		36.0 J	36.0 J
Ventricular Pacing	LV Only		40.0 J x2	40.0 J x4

Capture & Sense	**A**	**RV**	**LV**	**LV2**
Cap Confirm	Off		Off	
Pulse Amplitude	1.0 V		2.0 V	
Pulse Width	0.5 ms		0.5 ms	
AutoSense	On	On		
Sensitivity	Auto (A)	Auto (A)		

Diagnostics Summary Since 5 May 2021

AP	<1 %
LVP	>99 %
AMS Episodes	0
Mode Switch	0%
AT/AF Burden	0%

VT/VF Episodes: 0 Since 20 Oct 2020

	VT	VF
Episodes	0	0
ATP Delivered	0	0
Shocks Delivered	0	0

SVT Episodes: 0
Non-sustained Episodes: 0

No Alerts

Remote monitoring from being Powerfully connected to Patient centric outcomes.

Powerfully Connected

Bluetooth Enabled Remote monitoring empowers the patient to be Powerfully Connected with their physician at critical times.

Proactive Detection

Notification of Alerts through Bluetooth enabled Remote Monitoring leads to Prompt detection: No ongoing CRT pacing led to detection of Lead Dislodgement.

Early Intervention

With Bluetooth RM, 79% Reduction in Time to Clinical Decision:

Quick follow up with Lead Repositioning

Peace of Mind

With constant monitoring of Device Integrity and Functionality:

Reshaping the Patient Follow up care

Patient Centric Outcomes

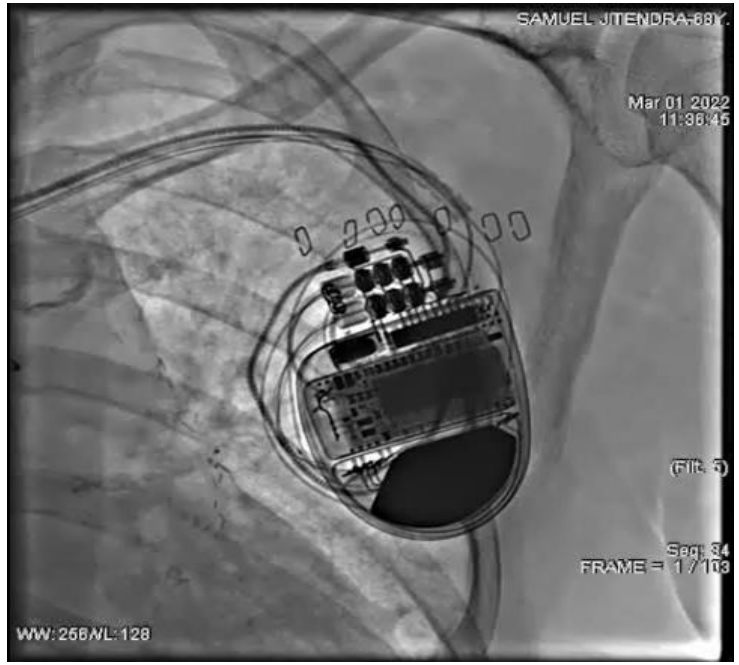
To live confidently and Freedom to go anywhere:

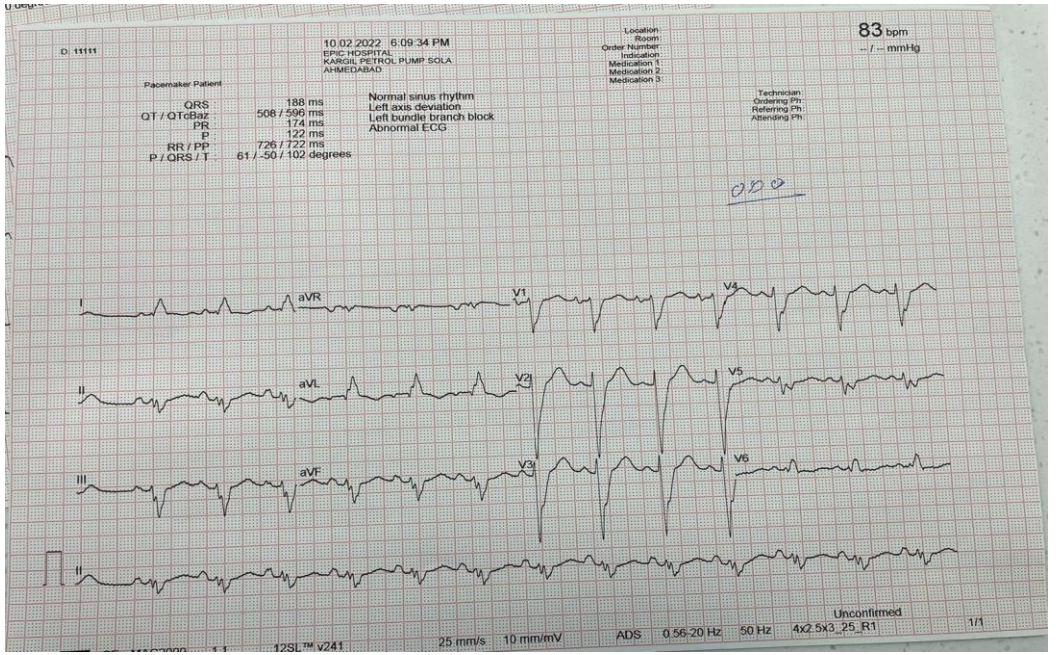
Empowering Patients with Smartphone enabled RM

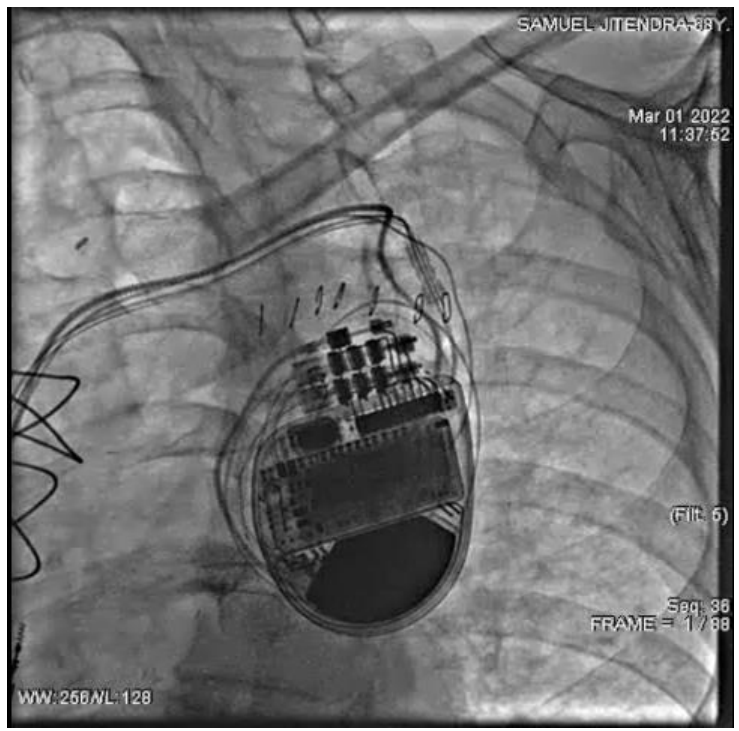
The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) Trial: The Value of Wireless Remote Monitoring With Automatic Clinician Alerts: George H.CrossleyMD* AndrewBoyleMD †HollyVitensePhD ‡YanpingChangMS §R. HardwinMeadMD ||CONNECT Investigators

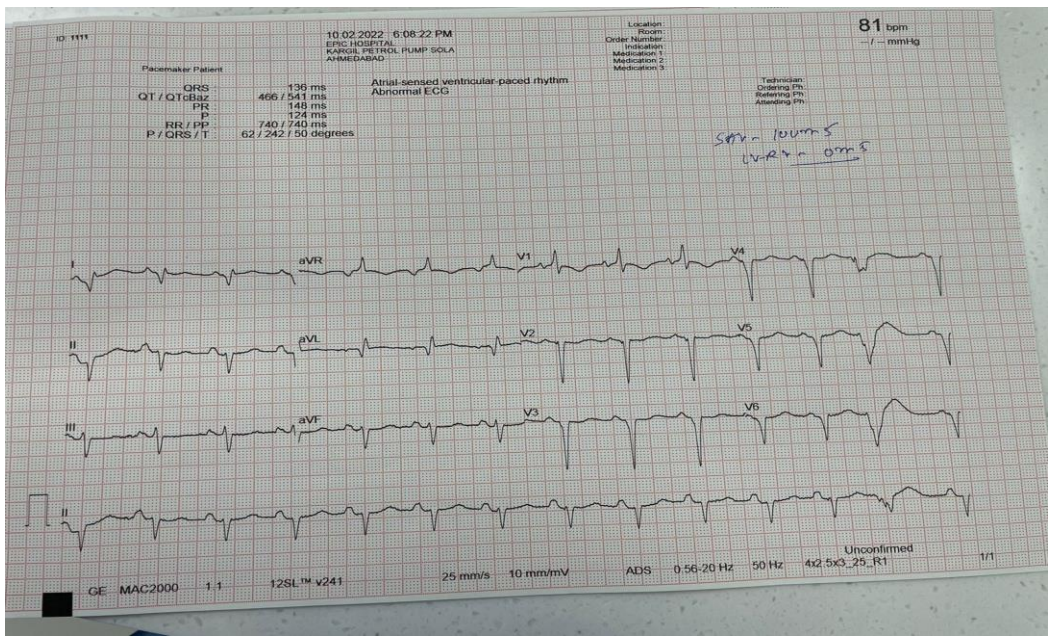
Case 2

- 70 year old man
- CABG in 2007 with Severe LV dysfunction.
- NYHA class 3 symptoms with LVEF 15%
- Sinus rhythm: LBBB with QRS duration of 160 msec
- Medtronic Ampia CRT-D implantation


SAMUEL JITENDRA 88Y.
Mar 01 2022
11:36:45
(Filt. 5)
Seq: 34
FRAME = 1 / 103
WW: 256 WL: 128


ID: 11111
10.02.2022 6:09:34 PM
EPIC HOSPITAL
KARGIL PETROL PUMP SOLA
AHMEDABAD
Pacemaker Patient
Location:
Room:
Order Number:
Indication:
Medication 1:
Medication 2:
Medication 3:
Technician:
Ordering Ph:
Referring Ph:
Attending Ph:
83 bpm
--- / --- mmHg
QRS 188 ms
QT / QTcBaz 508 / 596 ms
PR 174 ms
P 122 ms
RR / PP 726 / 722 ms
P / QRS / T 61 / -50 / 102 degrees
Normal sinus rhythm
Left axis deviation
Left bundle branch block
Abnormal ECG
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
Unconfirmed
12SL™ v241
25 mm/s
10 mm/mV
ADS
0.56-20 Hz
50 Hz
4x2.5x3.25_R1
1/1


SAMUEL JITENDRA 88Y.
Mar 01 2022
11:37:52
(Filt. 5)
Seq: 36
FRAME = 1 / 98
WW: 256 WL: 128


ID: 11111
10.02.2022 6:08:22 PM
EPIC HOSPITAL
KARGIL PETROL PUMP SOLA
AHMEDABAD
Pacemaker Patient
Location:
Room:
Order Number:
Indication:
Medication 1:
Medication 2:
Medication 3:
Technician:
Ordering Ph:
Referring Ph:
Attending Ph:
81 bpm
--- / --- mmHg
QRS 136 ms
QT / QTcBaz 466 / 541 ms
PR 148 ms
P 124 ms
RR / PP 740 / 740 ms
P / QRS / T 62 / 242 / 50 degrees
Atrial-sensed ventricular-paced rhythm
Abnormal ECG
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
Unconfirmed
GE MAC2000
12SL™ v241
25 mm/s
10 mm/mV
ADS
0.56-20 Hz
50 Hz
4x2.5x3.25_R1
1/1

Recurrent Shock through the device

Treated VT/VF Episode #126

Device: Compia MRI Quad CRTD DTMC2QQ Serial Number: RPF622465S Date of Visit: 15-May-2023 15:56:47
Patient: SAMUEL JITENDRA 68/M ID: Episode #126 - VT (+SVT) Chart speed: 25.0 mm/sec

SW034 Software Version 8.5 (3.1) Copyright © Medtronic, Inc. 2020 15-May-2023 15:53:54 Page 1

Treated VT/VF Episode #126

Device: Compia MRI Quad CRTD DTMC2QQ Serial Number: RPF622465S Date of Visit: 15-May-2023 15:56:47
Patient: SAMUEL JITENDRA 68/M ID: Physician: DR.ANOOP GUPTA 9825611033

Episode #126: 09-May-2023 11:40:00

Episode Summary

Initial Type	VT (+SVT) (spontaneous)
Predetect Duration	5 sec
Duration	1.6 min
A/V Max Rate	353 bpm/176 bpm
V. Median	176 bpm (340 ms)
V. Stability	0 ms - 10 ms
Activity at onset	Rest, Sensor = 78 bpm
Last Therapy	VT Rx2: CV, Successful

Device was in Mode Switch prior to detection.

Initial VT/VF Detection Withheld By
AFib/AFlutter

Therapies	Delivered	Charge	Ohms	Energy
VT Rx 1 Burst	Seq 1 to Seq 3			
VT Rx 2 CV	20.1 J	4.18 sec	55 ohms	0.0 - 20 J
Termination				

Wavelet Measurements Prior to Initial VT/VF Detection
Template Status: No template available

Parameter Settings		Initial	Redetect	V. Interval (Rate)
VF	On	30/40	12/16	300 ms (200 bpm)
FVT	Off			
VT	On	16	12	360 ms (167 bpm)
Monitor	Monitor	32		450 ms (133 bpm)

PR Logic/Wavelet

AF/Afl	On
Sinus Tach	On
Other 1:1 SVTs	Off
Wavelet	On, Match = 70 %
Template	None, Auto = Off
SVT V. Limit	260 ms

Other Enhancements

Stability	Off
Onset	Off
High Rate Timeout	
VF Zone Only	Off
All Zones	Off
TWave	On
RV Lead Noise	On+Timeout
Timeout	0.75 min

Polarity	RV
Pace Polarity	Bipolar
Sense Polarity	Bipolar

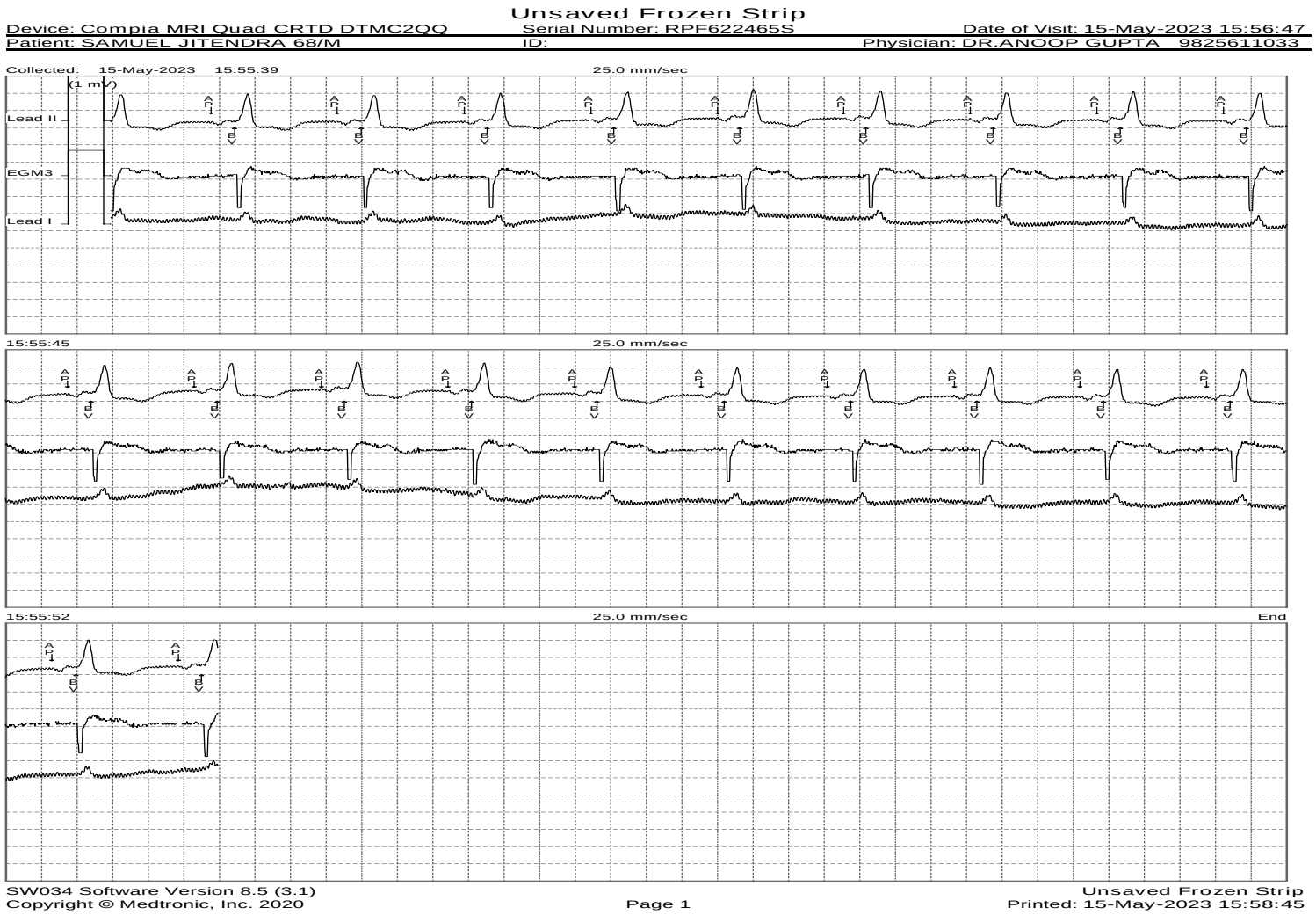
EGM	Source	Range
EGM1	Atip to Aring	+/- 8 mV
EGM2 (Wavelet)	Can to RVcoil	+/- 12 mV

Sensitivity	
Atrial	0.3 mV
RV	0.3 mV

SW034 Software Version 8.5 (3.1)

Treated VT/VF Episode #126
Printed: 15-May-2023 15:54:48

Following Atrial Fibrillation Management



Remote monitoring Can Significantly Improve Clinical Outcomes for HF Patients

THE LANCET

IN-TIME

Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial

*Gerhard Hindricks, Milos Taborsky, Michael Glikson, Ullus Heinrich, Burghard Schumacher, Amos Katz, Johannes Brachmann, Thorsten Lewalter, Andreas Goette, Michael Block, Josef Kautzner, Stefan Sack, Daniela Husser, Christopher Piorkowski, Peter Søgaard, for the IN-TIME study group**

Standard Care

+

Home Monitoring
- Automatic
- Daily
- Implant-based
- Multiparameter

>30% Reduction of Worsening of Clinical Status *(p=0.013)*

>60% Reduction of All-Cause Mortality *(p=0.004)*

Hindricks G et al., Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomized controlled trial. The Lancet 2014; 384(9943). http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2814%2961176-4/fulltext

IN-TIME Revealed Three Key Elements to Improve Clinical Outcome of HF Patients

IN-TIME

1  **Transmission**	Reliable transmission rate of at least 80% of all days	▪ Implant-based ▪ Automatic ▪ Daily
+		
2  **Procedure**	Disease and patient-relevant set of rhythm logical and technical parameters	▪ Multiparametric ▪ Relevant
+		
3  **Workflow**	Effective clinical workflow for fast patient contact and follow-up within 2 working days	▪ Specific ▪ Fast

Publication of Meta-Analysis of 3 Monitoring Trials using Remote Monitoring

TRUECOIN = TRUST + ECOST + IN-TIME

European Heart Journal (2017) **00**, 1–7
doi:10.1093/eurheartj/ehx015

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Daily remote monitoring of implantable cardioverter-defibrillators: insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST)

Gerhard Hindricks[1]*, Niraj Varma[2], Salem Kacet[3], Thorsten Lewalter[4], Peter Søgaard[5], Laurence Guédon-Moreau[3], Jochen Proff[6], Thomas A. Gerds[7], Stefan D. Anker[8], and Christian Torp-Pedersen[9]

Remote Monitoring - New meta-analysis confirms and explains significant survival benefit for ICD/CRT-D patients with heart failure

Main clinical results

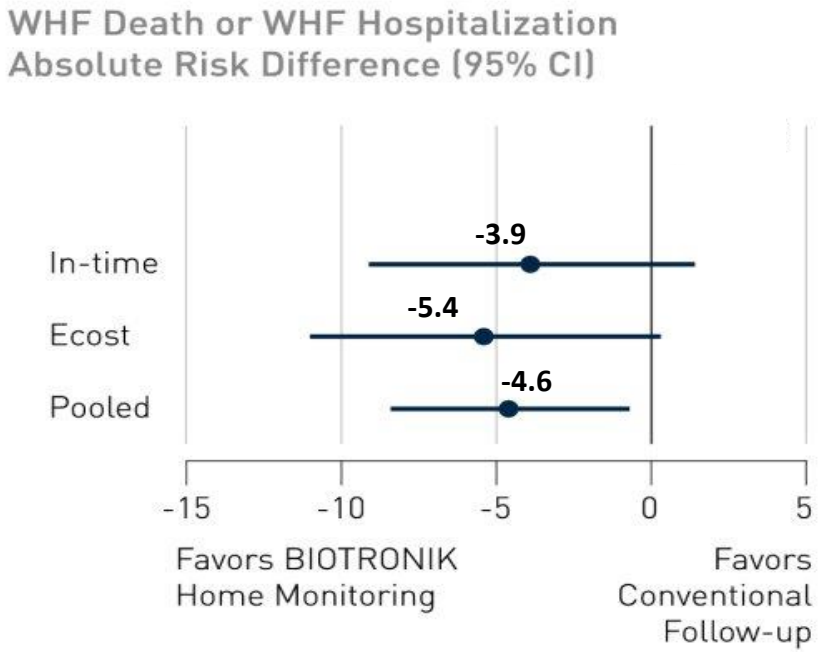
- Home Monitoring is associated with a significant reduction of clinically relevant endpoints
- This clinical benefit is mainly driven by prevention of heart failure exacerbation.

Clinical endpoint (at 12 months)	**relative** risk reduction	**absolute** risk reduction	
All-cause mortality	↓ 38%	↓ 1.9%	*p<0.05*
All-cause mortality or WHF hospitalization	↓ 36%	↓ 5.6%	*p<0.01*

WHF, Worsening Heart Failure

Hindricks G, Varma N, Kacet S, Lewalter T, Søgaard P, Guédon-Moreau L, Proff J, Gerds T, Anker S, Torp-Pedersen C.; Daily remote monitoring of implantable cardioverter-defibrillators: Insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST); European Heart Journal 2017, doi:10.1093/eurheartj/ehx015

Significant reduction of WHF death or WHF hospitalization with Remote Monitoring



4.6%
absolute reduction
of
WHF death or WHF hospitalization
at 1 year

95% CI: -8.4% to -0.7%],
p=0.02

Hindricks G, Varma N, Kacet S, Lewalter T, Søgaard P, Guédon-Moreau L, Proff J, Gerds T, Anker S, Torp-Pedersen C.; Daily remote monitoring of implantable cardioverter-defibrillators: Insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST); European Heart Journal 2017, doi:10.1093/eurheartj/ehx015

Underlying Mechanisms of the Truecoin Results

“Prevention of heart failure exacerbation” is the main driver for the observed benefits

TRUECOIN evaluated additional well-established endpoints that combine cause-specific deaths and any-, cv-, or WHF hospitalizations

TRUECOIN	Result:
All-cause death	sign.
CV death	n.s.
All-cause death or any hospitalization	n.s.
All-cause death or cv hospitalization	n.s.
All-cause death or WHF hospitalization	sign.
CV-death or cv hospitalization	n.s.
WHF death or WHF hospitalization	sign.

Only the combined End Points including „Worsening Heart Failure hospitalization“ are significant.

Further RCTs on remote monitoring have been published in 2016

- Opti Link study (EHJ 2016)
  - Usual care + automatic alerts for fluid accumulation
  - Usual care alone
- REM-HF study (ESC 2016 hot line session)
  - Usual care + weekly remote monitoring
  - Usual care alone
- MORE-CARE study (ESC 2016 hot line session + EJHF 2016)
  - Usual care + automatic alerts for fluid accumulation, atrial tachyarrhythmia and system integrity
  - Usual care + audible alerts for system integrity, low battery, excessive charge time, and VF detection/therapy off

Recommendations for RM considerations

COR	LOE	Recommendation
1	A	**In patients with CIEDs, RM is recommended as part of the standard of care.**
1	B-R	**In patients with CIEDs on RM, routine surveillance of lead function and battery status is recommended to ensure device integrity.**
1	C-EO	**In patients with CIEDs on RM with a device capable of continuous connectivity, connectivity should be maintained.**

2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic

Standard Care Supporting Evidence

- RM reduces the number of health care visits and increases follow-up adherence and patient retention.
- Early detection of atrial and ventricular arrhythmias useful in reducing inappropriate implantable cardioverter-defibrillator (ICD) shocks.
- No study to date has shown a reduction in appropriate ICD shocks with RM.
- Early detection and quantification of AF episodes and arrhythmia burden.
- Continuous connectivity allows individualized patient treatment and continuous updating of therapeutic strategy.

Prognosis and outcome

- The ability of RM to prevent disease progression and improve outcomes with HF is still controversial.

- Modern implantable devices continuously provide diagnostic information to monitor for HF decompensation, creating opportunities for early intervention prior to deterioration and hospitalization.

- Automatic multiparameter monitoring seems promising in prevention of HF exacerbation. This is consistent with the pooled analysis of 3 trials in which RM reduced all-cause mortality or worsening HF hospitalization.

Cost effective

- RM is generally regarded as cost-effective, as it results in reduction of in-hospital scheduled and emergency visits, reduction of diagnostic test burden, and reduction of follow-up duration and physician and nurse time.

- RM also reduces patient costs for travel to in-person visits, time off from work, and interruption of daily activities of patients and accompanying persons.

- Conflicting results do exist regarding the impact of RM on patient acceptance and quality of life.

Routine Surveillance

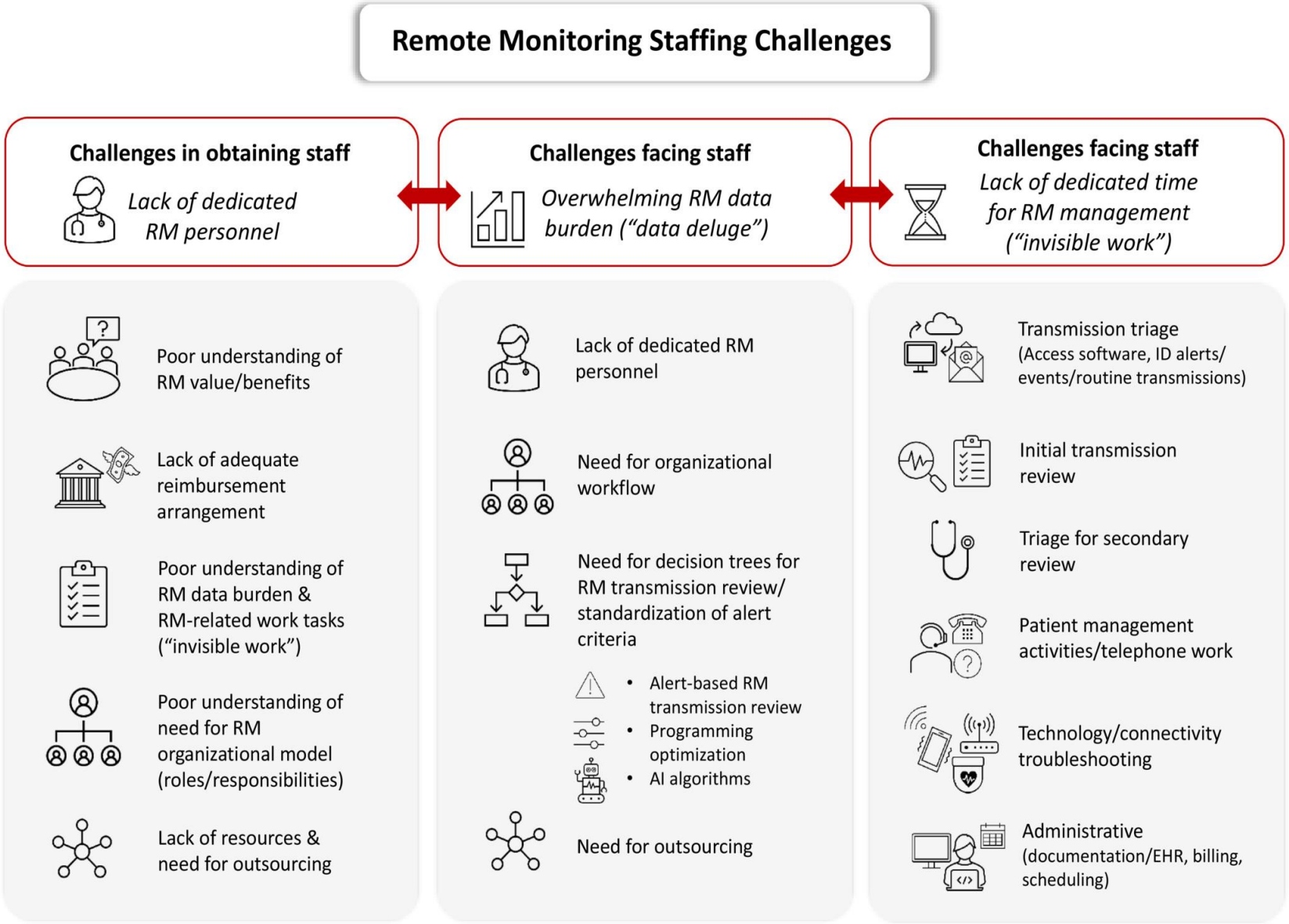
- RM allows effective and safe surveillance of device functioning with alerts for battery depletion, circuit disruption, and lead failure, ensuring device function and integrity.

- Early detection of malfunctions when the patient is asymptomatic may prevent catastrophic consequences, particularly in cases of lead or device advisory.

- RM allows continuous connectivity of pacing thresholds, allowing optimization of battery longevity.

Lack of Adoption

- Cost of RM-capable devices
- Increased service burden associated with specialized staffing
- Lack of reimbursement
- Lack of physician awareness, and/or the need for more evidence for improved clinical outcome.



Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

2015 HRS Guidelines: Personnel Based

Physician

- Provides final interpretation & documentation
- Has appropriate certification*
- Supervises mid-level providers

Mid-level Provider (NP/PA)

- Obtains medical history, reviews transmissions, make recommendations for management
- Participates in patient enrollment & education, interpretation of routine transmissions, documentation and billing
- Provides oversight of allied professionals

Allied Professional

- Has IBHRE certification or experience on par with certification
- Reviews data with criteria for involving physician or mid-level & patient contact

Ancillary staff

- Performs nonclinical actions:
  - Appointment reminders
  - Patient connectivity/troubleshooting
- Clinic technology/customer support
- Collects data for review

*American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology certification, American Board of Pediatrics Cardiology certification, or the International Board of Heart Rhythm Examiners (IBHRE) device certification.

2023 HRS Guidelines: Task Based (Implications for Staffing)

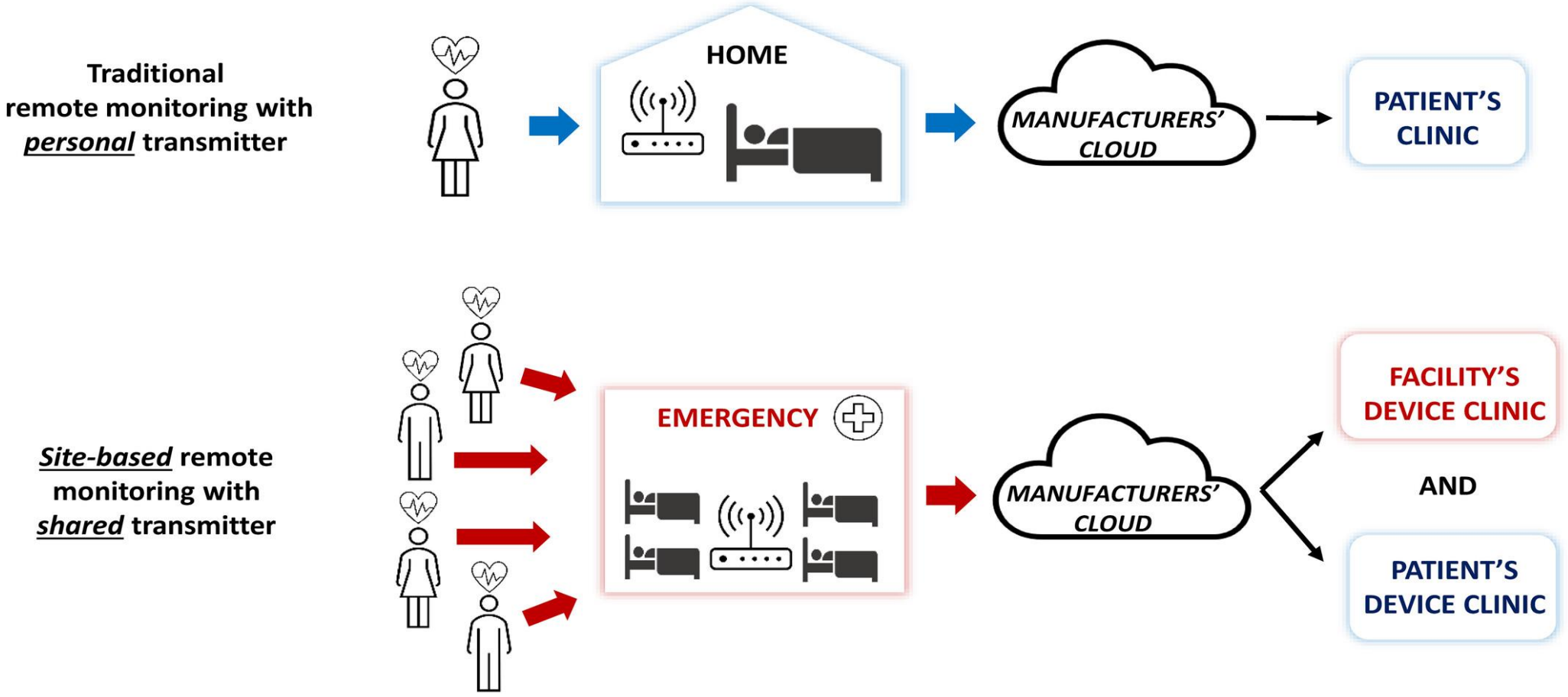
Task		*Issues Under Evolution*
Connectivity/Troubleshooting • Appointments • Connectivity • Patient questions	**Ancillary staff**	
Patient Education/Enrollment • What is remote monitoring? • Why is it needed? • Choice of monitor	**APP RN or Device Tech**	

CIED Data Triage & Review
• Website monitoring
• Initial data processing
• Initial communication with health care team
	Device Technician or RN	***Data Triage & Review, options*:**
		• Third-party software
		  • Single web-based data portal
		  • Device and patient management

Final Sign-Off • Final interpretation • Final communication with health care team • Documentation for billing **Alert Management** • Patient calls • In-office evaluations • Charting and communication	**Physician, APP/ Physiologist**	***Final sign-off*** • Interpretation (middleware vs in-EHR) • Information interoperability (between EHRs) • Closing the loop with patients ***Alert Management*** • In-office CIED management • Hospital-based remote CIED interrogations • After-hours alert management

Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Site- based Remote monitoring



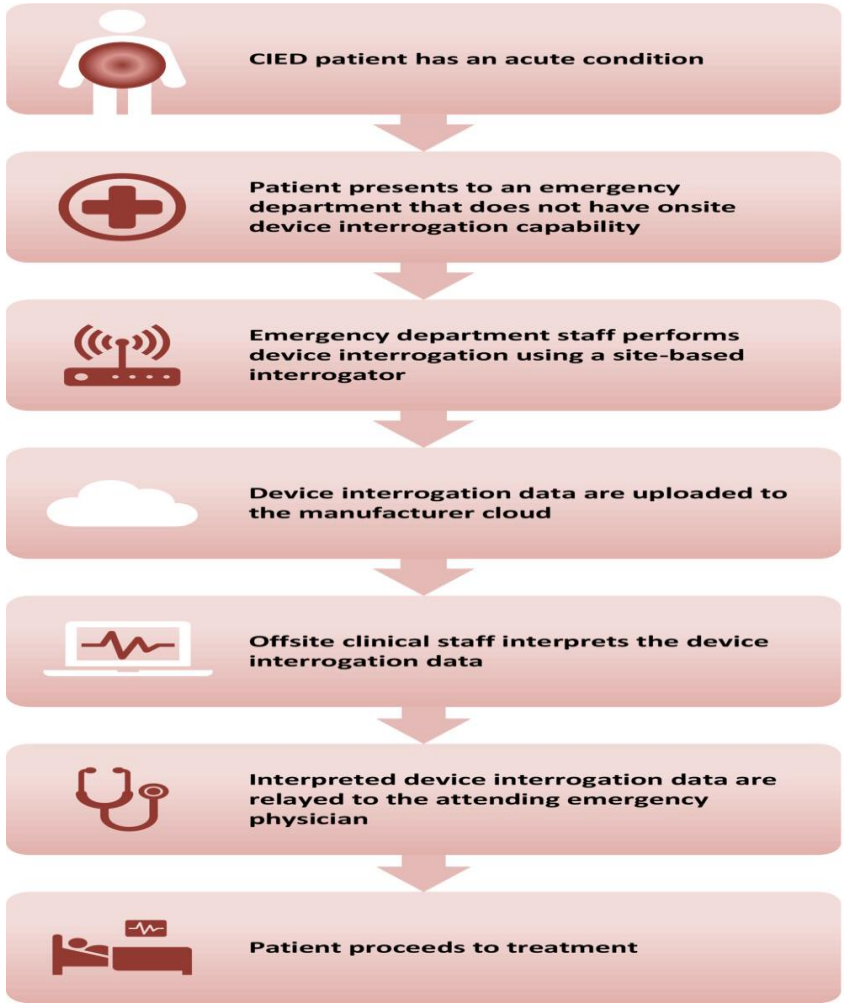
Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Alert based Remote Monitoring

1. Near perfect connectivity

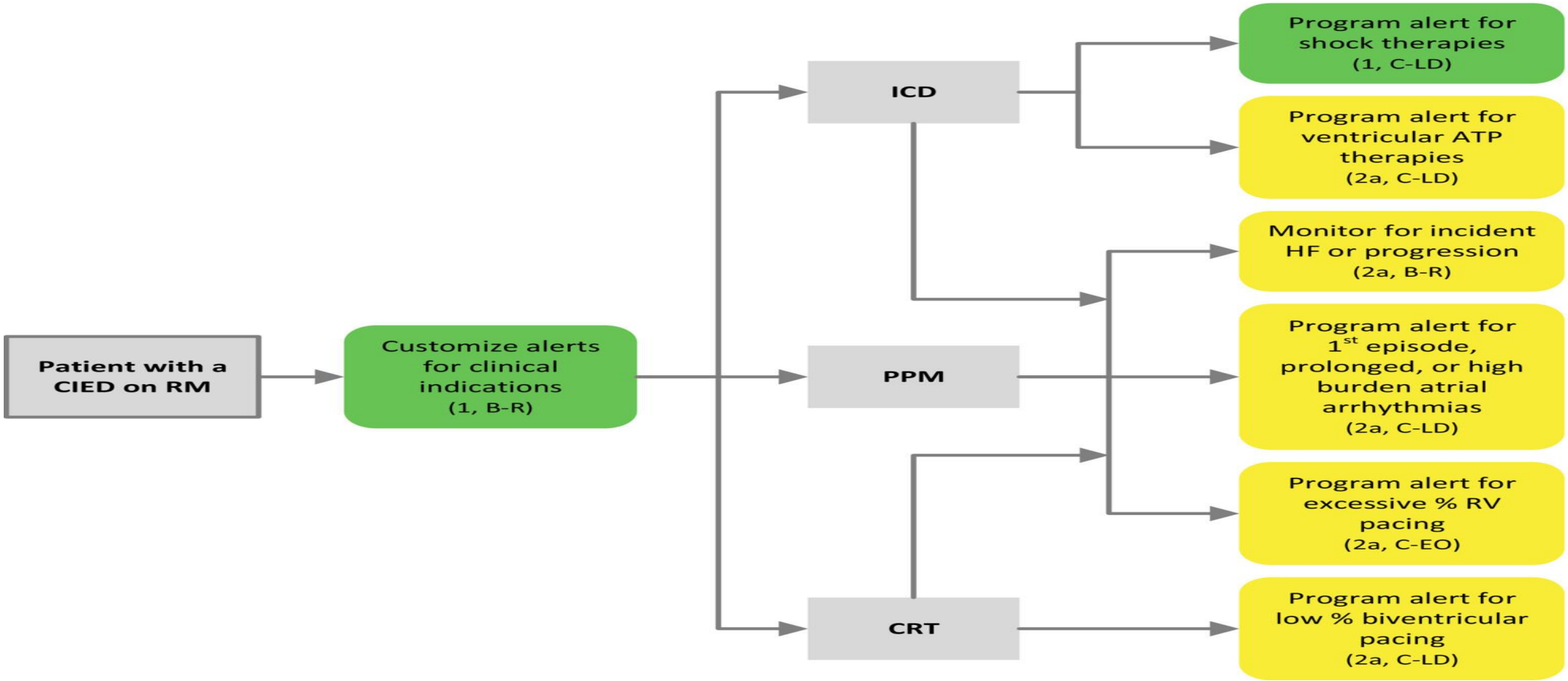
2. Robust systems to assure connectivity from manufacturers.

3. Excellent patient compliance



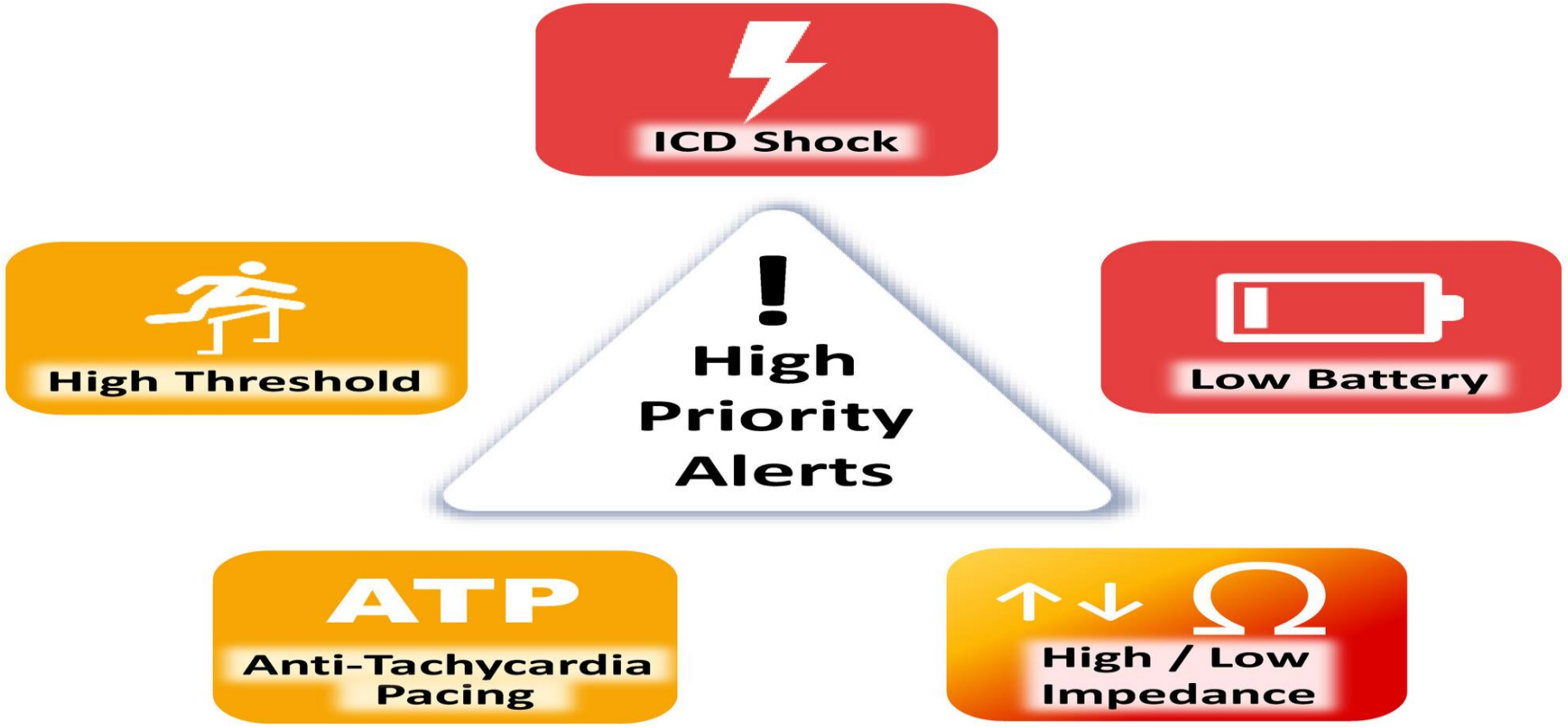
Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Programming considerations



Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Managing Alerts

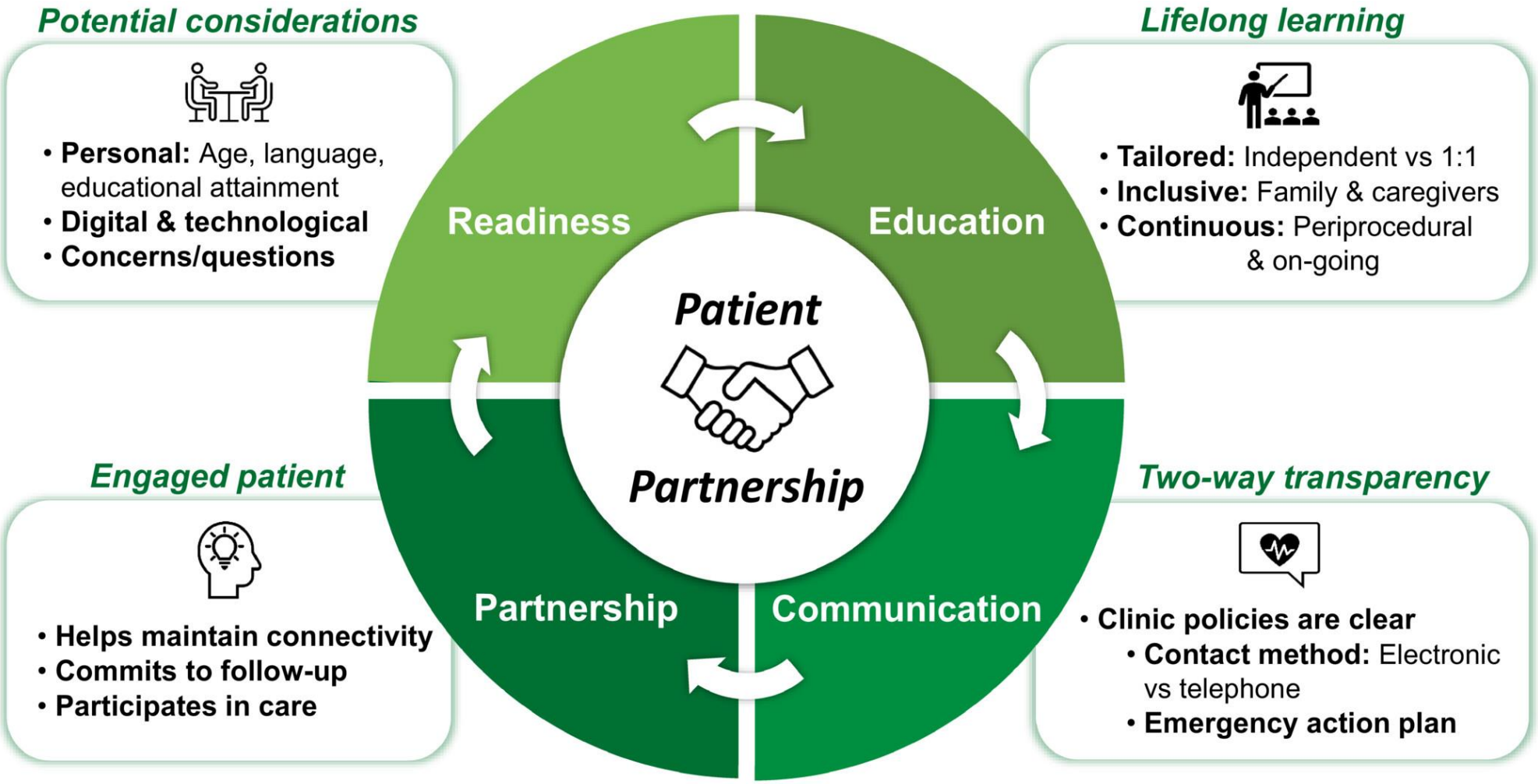


Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Minimizing alerts for nonactionable events

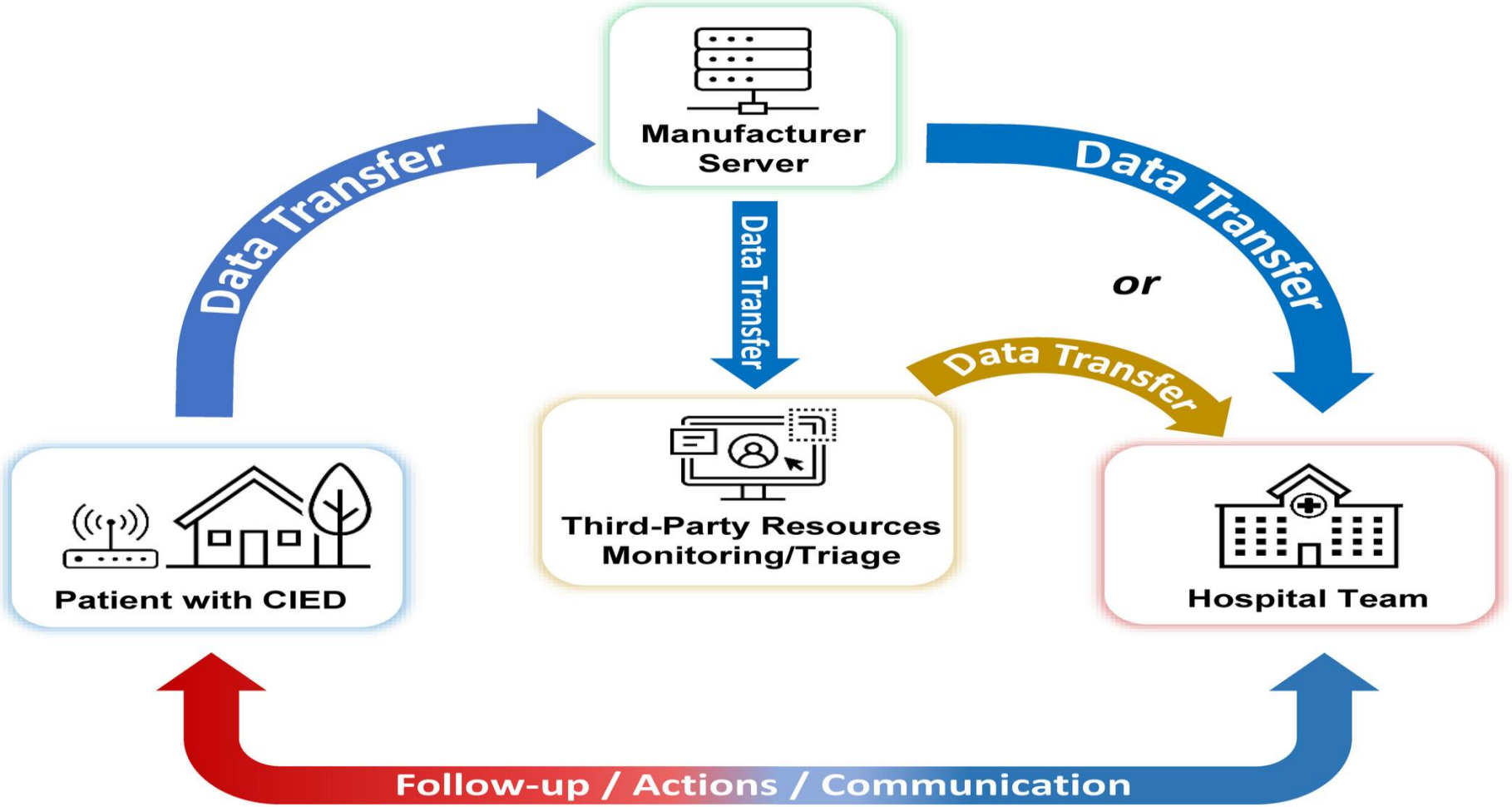
Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Patient Education



Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Third party Resources



Journal of Arrhythmia, First published: 19 May 2023, DOI: (10.1002/joa3.12851)

Conclusion and Take home message

- RM technologies are evolving quickly

- Research studies should be performed to determine optimal models.

- Value can be defined in terms of;
  - Patient satisfaction
  - Cost efficiencies
  - improved patient outcomes

- Transition from route RM to alert based (High-value visits)