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Telemonitoring and its value in the management of heart failure patients

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20 let CRT ČR

12. 6. 2019

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I: What is the real added value of remote control in HF patients?

The real role of remote monitoring in common clinical practice : 2019

1. In no case does it replace acute patient management

2. It is important to realize that this is not really an online data

3. Remote control significantly helps to resolve changes in health status (AF, VT), incipient decompensation of heart failure and also major changes in the technical condition of CRT systems

4. Rationalizes outpatient patient controls

5. It is always necessary to keep in mind that the basis of patient management with CRT and HF is clinical medicine

Objectives of Remote Monitoring

1 Improving Monitoring Efficiency

By safely replacing in-office follow-ups

by remote follow-ups

2 Improving Patient Outcome

By detecting events as early as possible

using continuous monitoring

Reduce healthcare utilization

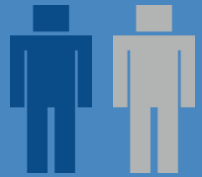
Up to **1 in 4** CRT-D/ICD device patients may visit the Emergency Room[1]

BASELINE

35%[2]
potential reduction in ER visits

REMOTE MONITORING

Up to **1 in 2** CRT-D/ICD device patients may require a hospitalization [1]



20%[3]
potential reduction in all-cause 3-year rehospitalization

18%[1]
potential reduction in hospital length of stay

[1] *Crossley GH, et al. J Am Coll Cardiol. 2011;57:1181-1189.*
[2] *Landolina M, et al. Circulation. 2012;125:2985-2992.*
[3] *Akar J, et al. Presented at HRS 2014 (LB03-03).*

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I. INTERNÍ KLINIKA KARDIOLOGICKÁ
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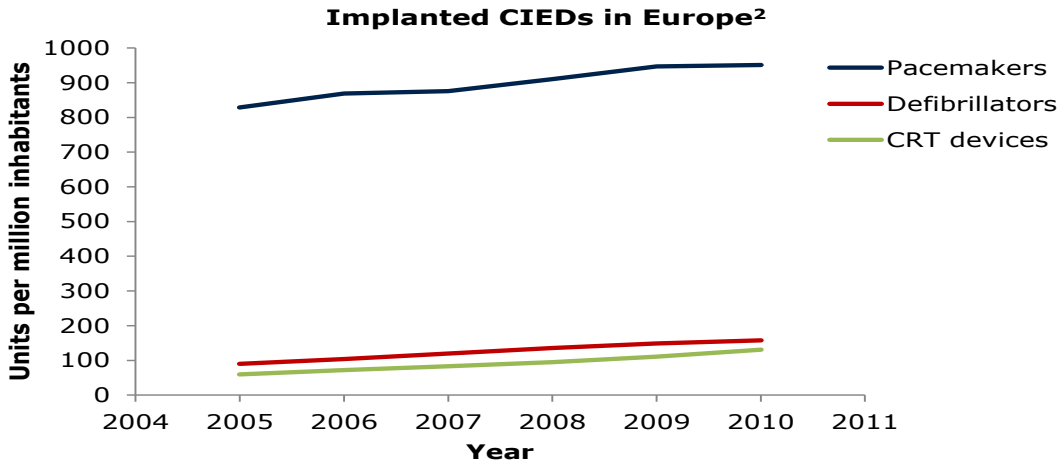
Demand for CIED follow-up services is growing due to the age-related increase in the prevalence of cardiac conditions

- The prevalence of cardiac conditions is increasing; e.g., HF prevalence is projected to increase 25% between 2010 and 2030 in the US[1]
- The number of implanted CIEDs is increasing[2]
- CIED follow-up is mandatory[3]
- The logistics of CIED follow-up place a substantial and increasing burden on the cardiovascular community[3]



CIED: cardiovascular implantable electronic device; CRT: cardiac resynchronization therapy

[1]Heidenreich PA *et al*. *Circulation* 2011;123(8):933-44. [2]Dubner S *et al*. *Europace* 2012;14(2):278-93. [3]Wilkoff BL *et al*. *Heart Rhythm* 2008;5(6):907-25

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II: Do we have enough persistent scientific data on the real effectiveness of remote control?

Remote Follow-Up: Clinical Evidence – I.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Randomized trials—PMs							
PREFER[9]	2009	Randomized, prospective, multicenter	897	VVI/DDD PMs Medtronic CareLink RM	Mean time to first diagnosis of CAE, comparing the RM arm and the control arm	FU: 375 ± 140 d Mean time to first diagnosis of CAE was 5.7 mo in the RM arm vs 7.7 mo in the control arm $P < 0.001$	Mean time to first diagnosis of CAE was shorter in the RM arm
COMPAS[25]	2011	Randomized, multicenter	538	DDD PMs indications, no PM dependents Biotronik HM	MAE: hospitalization for PM-related complications, CV events, and death Incidence of each MAE RM reduction of in-office visits	FU: 18 mo MAE: 17.3% in the RM arm vs 19.1% in the control arm ($P < 0.01$ for non-inferiority Hospitalization due to PM complications in the RM arm (0.4%) vs the control arm (2.8%) $P < 0.05$ Mean number of unscheduled FUs per patient per year: 56% lower in the RM arm $p < 0.001$	RM was safe and reduced the number of in-office visits RM enabled earlier detection of clinical and device-related adverse events
Randomized trials—ICDs							
TRUST[6,15,16,26]	2010	Randomized, prospective, multicenter	1,339	VVI/DDD ICDs, no PM dependent Biotronik HM	Total in-hospital device evaluations Overall adverse event rate Time from event onset to physician evaluation	In-hospital device evaluation was 2.1 per patient per year in the RM arm vs 3.8 per patient per year in the control arm $p < 0.001$ Overall adverse event rate was 10.4% in both groups at 12 mo $p = 0.005$ for non-inferiority RM reduced event detection delay by >30 d $p < 0.001$	RM was safe in supplanting "routine" in-office visits, enabling early event detection in ICD recipients

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – II.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
CONNECT[21]	2011	Randomized, prospective, multicenter.	1,997	ICDs and CRT-Ds Medtronic Carelink RM	Time from a clinical event to a clinical decision Evaluated hospitalization LOS	22 d (in-office arm) vs 4.6 d (RM arm) $p<.001$ Health care use for CV reasons: 4 d (in-office arm) vs 3.3 d (RM arm) $p<.001$ LOS per hospitalization was 3.2 d in the RM arm vs 4.3 d in the in-office arm $p = .002$	RM reduced the time to a clinical decision RM reduced the mean LOS
ECOST[23] Clinical aspects	2012	Randomized, prospective, multicenter	433	ICDs Biotronik HM	Incidence of MAE (all-cause and CV death) Procedure-related complications and device-related adverse events	FU: 24.2 mo MAE: 40.3% vs 43.3% in the RM arm vs in the control arm $p<0.05$ (non inferiority) Appropriate and inappropriate shocks delivered were 71% lower in the RM arm $p < 0.05$ Battery longevity increased in the RM arm $p<0.02$ 76% reduction of capacitor charges	RM was as safe as standard FU RM reduces appropriate and inappropriate shocks
Economic aspects	2014		310		Economic impact of RM on patients with ICD	Nonhospital costs: RM: €1695 ± 1131 $p<0.04$ Conventional: €1952 ± 1023 Hospital costs: RM: €2829 ± 6382 Conventional: €3549 ± 9714 $p = .46$ Savings were increased to €494 by adding the ICD to nonhospital costs or to €315 per patient per year by adding the monitoring system	RM reduced mean nonhospital costs per patient per year RM did not significantly reduce the hospital costs per patient per year

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – III.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
EVOLVO[27]							
Clinical aspects	2012	Randomized, prospective, multicenter	200	LVEF ≤35% Medtronic ICDs or CRT-Ds with thoracic impedance measurement capabilities (OptiVol)	Rate of the emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events Economic impact of RM on patients with ICD and heart failure	FU: 16 mo Total events: 0.59 vs 0.93 events per patient per year in the RM arm vs in the control arm $p = 0.005$ Number of urgent visits per patient per year for heart failure, arrhythmias, or ICD-related: 4.4 in the RM arm vs 5.7 in the control arm $p < 0.001$ Time from ICD alert to review: 1.4 d in the RM arm vs 24.8 d in the control arm $p < 0.001$	RM reduced the number of emergency department or urgent in-office visits and health care use RM increased the efficiency of health care No significant annual cost savings for the health care system
Economic aspects	2013					Costs: €1962 vs €2130 $p = 0.8$ Costs for patients: €291 vs €381 $p < 0.01$ Cost utility: patients in the RM arm had a cost saving of €888 per patient and gained 0.065 QALYs more over 16 months	Significant reduction in the annual cost for patients and gained QALYs in the RM arm

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – IV.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
REFORM[19] (second analysis)	2013	Randomized, parallel Quarterly clinic visits (Q arm) vs yearly clinic visits (Y arm)	155	ICD implanted according to MADIT II criteria	Scheduled and unscheduled ICD visits Difference in quality of life scores at baseline and after 27 mo Total and CV mortality Rate and length of all-cause and CV hospitalizations	FU: 24 mo FU visits reduced by 58% (3.8 vs 1.6 visits per patient pe year in the Q arm vs in the Y arm) $p < 0.001$ Unscheduled FU per patient year was 0.27 in the Q arm vs 0.64 in the Y arm $p = 0.03$ All-cause mortality was not different between groups Y group did not exceed 1 additional visit per patient per year	RM safely reduces the ICD FU burden for 27 mo after implantation Favorable impact of RM on the quality of life No impact on mortality and hospitalization rate
Calò et al[28]	2013	Prospective, randomized	233	Biotronik, Boston Scientific, Medtronic, St Jude Medical	Assess current direct costs of 1-y ICD FU based on RM compared with conventional quarterly in-hospital FU from the hospital and patient perspective	FU required 47 min per patient per year in the RM arm vs 86 min per patient per year in the control arm $p < 0.03$ The costs associated with RM FU vs standard FU was \$103 ± 27 per patient per year vs \$154 ± 21 per patient per year $p < 0.01$ Overall cost savings for RM vs standard FU: \$97 ± 121 per patient per year vs \$287 ± 160 per patient per year $p < 0.001$	RM significantly reduced: The time spent by hospital staff The costs of the hospital and pt

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – V.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
IN-TIME[29]	2014	Randomized, parallel	716	ICDs/CRT-Ds Biotronik HM, NYHA class II/III, LVEF ≤35%	Primary outcome measure was a composite clinical score combining all-cause mortality, overnight hospital admission for heart failure, change in NYHA class, and change in patient global self-assessment Secondary outcome measures were all-cause mortality, hospital admission, and heart failure admissions	At 1-y FU, 18.9% of patients in the HM group vs 27.2% in the control group had worsened symptoms $p = 0.01$ 1-y all-cause mortality in the telemonitoring group was 3.4% vs 8.7% in the control group $p = .004$ RM did not affect heart failure admissions $p = .38$	Patients on HM less likely to reach the composite end point Patients on HM had lower mortality HM did not reduce heart failure admissions
Registries, Mega-cohort observational studies							
AWARE[24]	2007	Retrospective analysis	11,624	PMs, ICDs, CRT-Ds Biotronik HM	Time to detection of events and impact on physician workload, comparing the RM arm vs the standard care arm	Mean time from the last FU to detection of an event was 26 d in the RM group compared with the usual FU period	RM improved safety and optimized the allocation of health resources.
ALTITUDE[30]	2010	Nonrandomized networked patients	185,778	ICDs/CRT-Ds with LATITUDE (Boston Scientific)	Patient survival	1- and 5-y survival rates were 50% reduced in non-RM patients $p < 0.001$	RM improves survival
MERLIN[31]	2015	Nonrandomized networked patients	269,471 (consecutive)	PPMs, ICDs/CRT-Ds with MERLIN	Survival according to the level of adherence to RM and device type	>75% adherence to RM promoted best survival $p < .001$ Pts with PM gained similar survival advantage with >75% adherence to RM $p < 0.001$	RM-mediated survival is dose dependent on the degree of adherence but not on CIED complexity

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – VI.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Observational studies							
Fauchier et al[32]	2005	Nonrandomized database analysis	502	ICDs Biotronik HM	Calculation of costs related to ICD FU, including medical services and transportation compared with the expected costs of RM	RM was associated with a $2149 saving per patient in 5 y. Even considering an extra cost of $1200 for acquiring the technology, a breakeven point could be reached after 33.5 mo	RM reduces medical and transportation costs compared with standard ICD FU
Raatikainen et al[33]	2008	Observational	41	ICDs Medtronic Carelink RM	Assess whether RM offers a safe, practical, and cost-effective alternative to the in-office FU of patients with ICD	To complete FU, RM required: Less time from patients: 6.9 ± 5.0 min vs 182 ± 148 min $p < 0.001$ Less time from physicians: 8.4 ± 4.5 min vs 25.8 ± 17.0 min $p < 0.001$	RM reduces costs compared with standard ICD FU (saving of €524 per patient per year, 41% of the cost of standard FU)

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100. http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – VII.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
HomeGuide Registry[17,18]	2013 2014	Multicenter, prospective registry	1650	PMs, ICDs, CRT-Ds Biotronik HM	To estimate clinical effectiveness in event detection and management of devices with RM To analyze outpatient clinic workload and the impact on resource consumption To test a specific nurse-based workflow model	Clinical events: RM sensitivity: 84.3% PPV: 97.4% RM incremental utility: 0.56 RM detected 95% of asymptomatic events and 73% of AEs Manpower of 55.5 min per health personnel per month for every 100 patients 15.4 min per patient to detect 0.43 AEs (RM arm) vs 60.5 min per patient to detect 0.16 AEs (in-person arm) Nurses reviewed 70% of transmissions (15% submitted to the physician)	RM effectively detected and managed clinical events $p < 0.001$ The nurse-based workflow model was safe, effective, and efficient
Patient satisfaction							
Marzegalli et al[34]	2008	Observational study	67	ICDs	Assess the ease of use of the system and patient and clinician acceptance and satisfaction	78% of the patients preferred remote FU to in-clinic visits; 100% found it easy to use	RM reduces FU time as compared with standard in-hospital visits

Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Remote Follow-Up: Clinical Evidence – VIII.

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Ricci et al[35]	2010	Observational	119	PMs, ICDs, and CRTs in RM after 1 y of FU	To evaluate patient acceptance and satisfaction through a self-administered questionnaire (HoMASQ)	The mean scores were (range 0–4) 3.0 ± 0.9 for relationship, 3.4 ± 0.6 for ease of use, 3.4 ± 0.9 for psychological aspects, 3.4 ± 0.8 for clinical implication, and 3.4 ± 0.8 for overall satisfaction	Patients showed a high level of acceptance and satisfaction for all investigated areas
Petersen[36]	2012	Observational	474	Medtronic ICD or CRT-D and successful Carelink transmissions	To evaluate patient satisfaction with remote FU	385 of 474 (81.2%) patients responded to the questionnaire 25% of patients made unscheduled transmissions (for shock, alarm, palpitation, or other reasons)	95% were very content or content with remote FU 84% expressed desire for clear and prompt communication from the monitoring center
Morichelli et al[37]	2014	Observational	163	Recipients of ICDs in RM after 20 mo	To evaluate patient acceptance and satisfaction through a self-made questionnaire (HoMASQ) with another proprietary system	The mean scores were (range 0–4) 3.3 ± 0.7 for relationship, 3.5 ± 0.5 for ease of use, 3.5 ± 0.4 for psychological aspects, 3.4 ± 0.6 for clinical implication, and 3.8 ± 0.3 for overall satisfaction	Patients showed a high level of acceptance and satisfaction for all investigated areas

AE = actionable event; CAE = clinically actionable event; CRT-D = cardiac resynchronization therapy with defibrillator; CV = cardiovascular; DDD = dual-chamber; FU = follow-up; HM = home monitoring; HoMASQ = Home Monitoring Acceptance and Satisfaction Questionnaire; HR = hazard ratio; ICD = implantable cardioverter-defibrillator; LOS = length of stay; LVEF = left ventricle ejection fraction; MADIT II = Multicenter Autonomic Defibrillator Implantation Trial II; MAE = major adverse event; NYHA = New York Heart Association; OR = odds ratio; PM = pacemaker; PPM = permanent pacemaker; PPV = positive predictive value; QALY = quality-adjusted life year; RM = remote monitoring; VVI = ventricle paced, ventricle sensed, pacing inhibited if beat sensed.
*The table summarizes clinical trials discussed in the text.

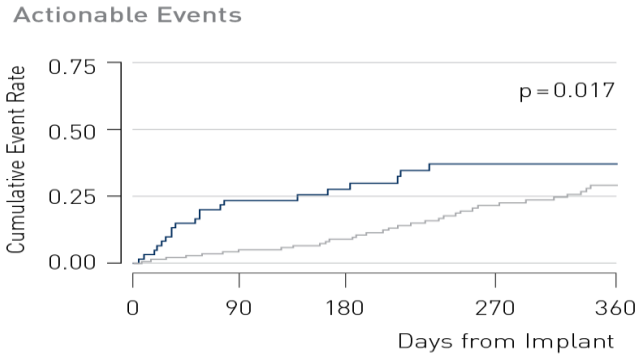
Slotwiner D, et al. Heart Rhythm 2015;12:e69–e100.
http://dx.doi.org/10.1016/j.hrthm.2015.05.008

Daily Transmission Ensures Early Detection

Superior Monitoring by Design

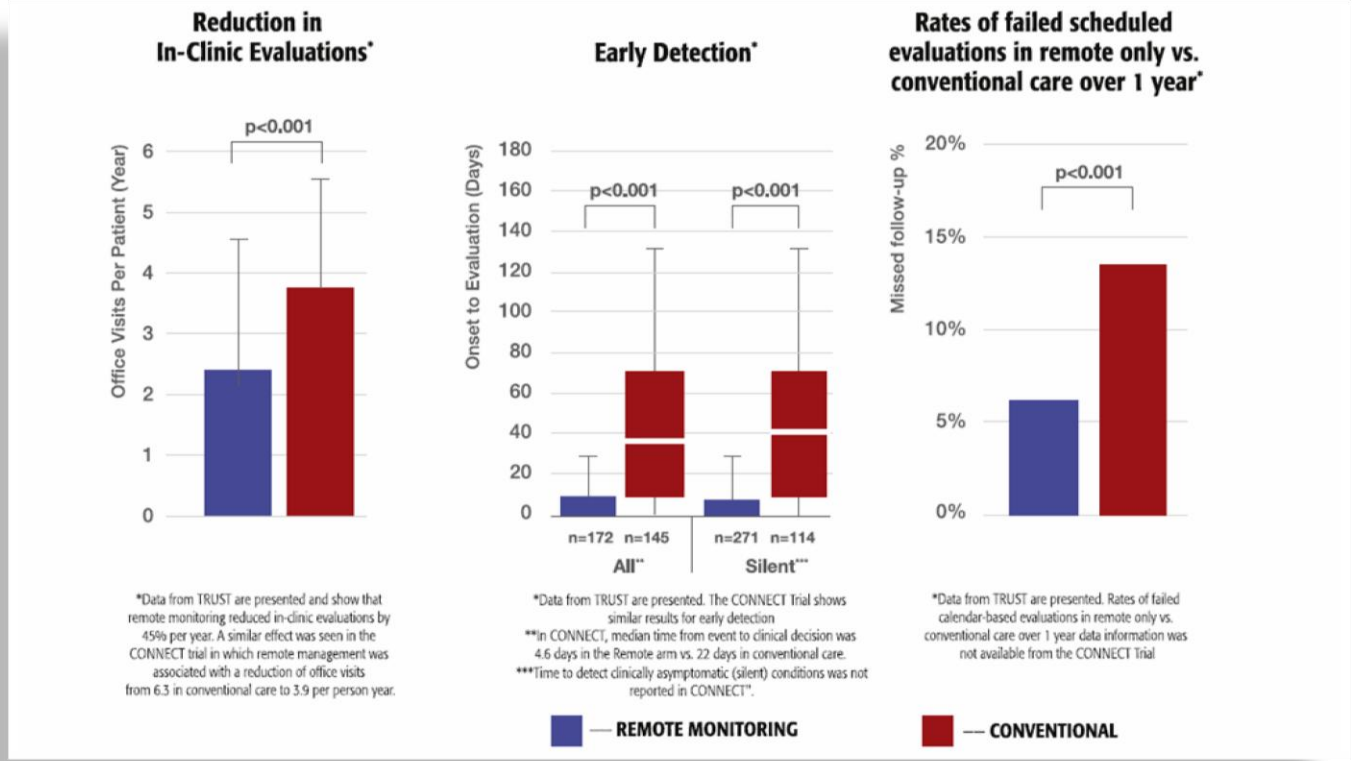
- Automatic data transmission from day one
- > 90% transmission reliability
- Daily automatic alert notification on monitoring incompliance

Daily Data Transmission Offers Superior Detection of Actionable Events



Varma N. et al., The TRUST trial, Circulation 2010, 122: 325-332.

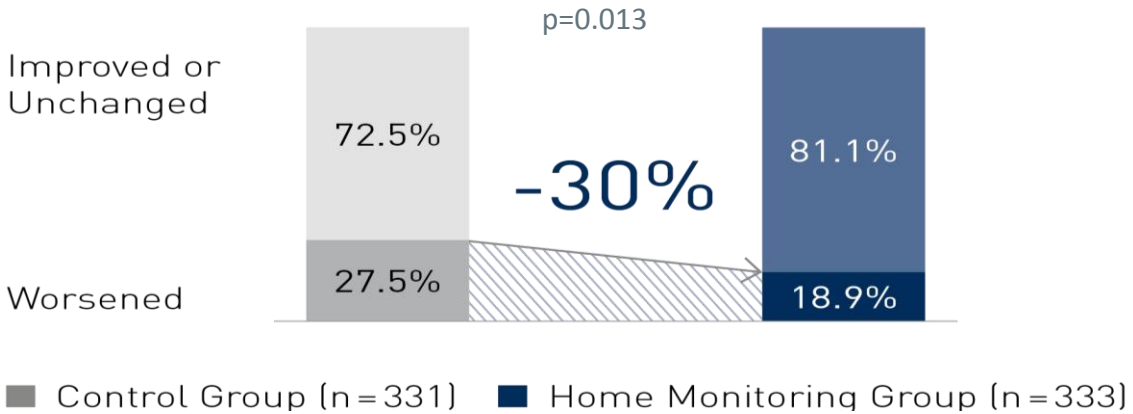
Benefits of remote monitoring



IN-TIME Study Results

Home Monitoring Enables a Significant Reduction of Worsening of Clinical Status

Result of Primary Endpoint: **Modified Packer Score**



Modified Packer Score

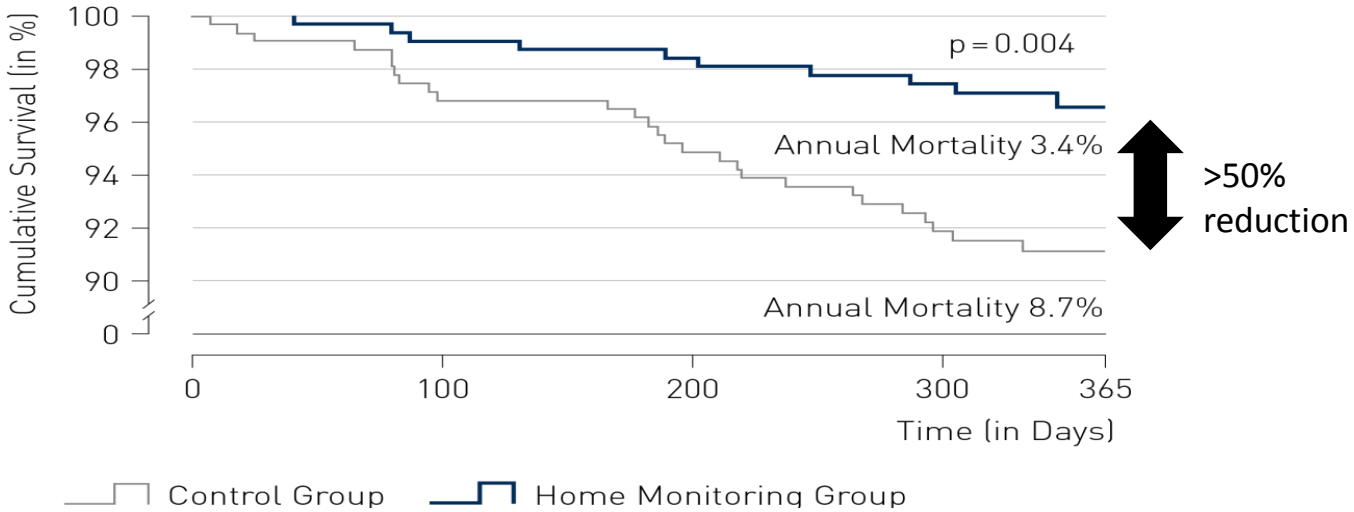
Patients are classified as "worsened" in case of:

- Death
- Overnight hospitalization for worsening heart failure
- Worsening in NYHA Class
- Deterioration in patient's global self assessment

Hindricks G et al., Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. The Lancet 2014; 384(9943).
http://www.thelancet.com/journals/lancet/article/PIIS01406736%2814%2961176-4/fulltext

IN-TIME Results

All-Cause Mortality reduction enabled by Home Monitoring



Hindricks G et al., Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. The Lancet 2014; 384(9943).
http://www.thelancet.com/journals/lancet/article/PIIS01406736%2814%2961176-4/fulltext

Truecoin (TRUST, ECOST, IN-TIME)

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

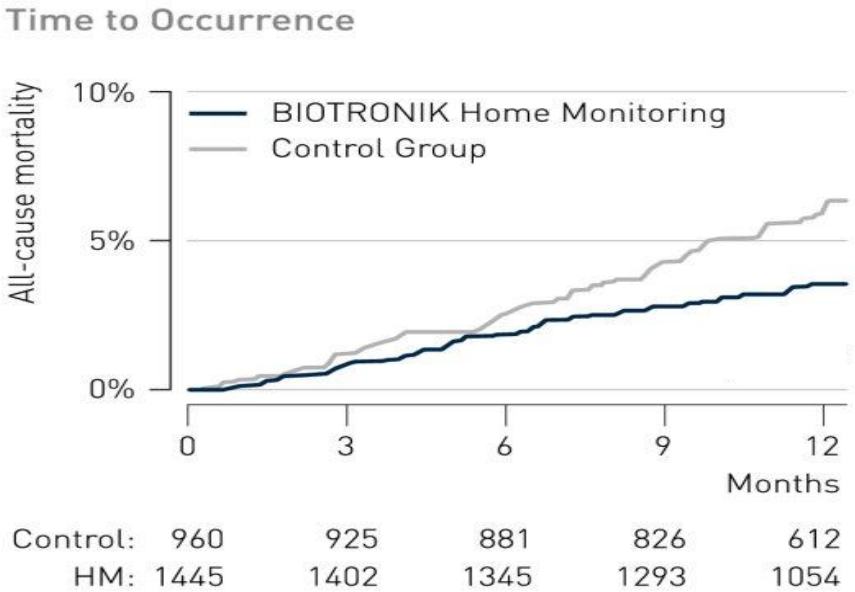
European Heart Journal (2017) **00**, 1–7
doi:10.1093/eurheartj/ehx015

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]

Significant Reduction of All-cause Mortality with BIOTRONIK Home Monitoring



38%

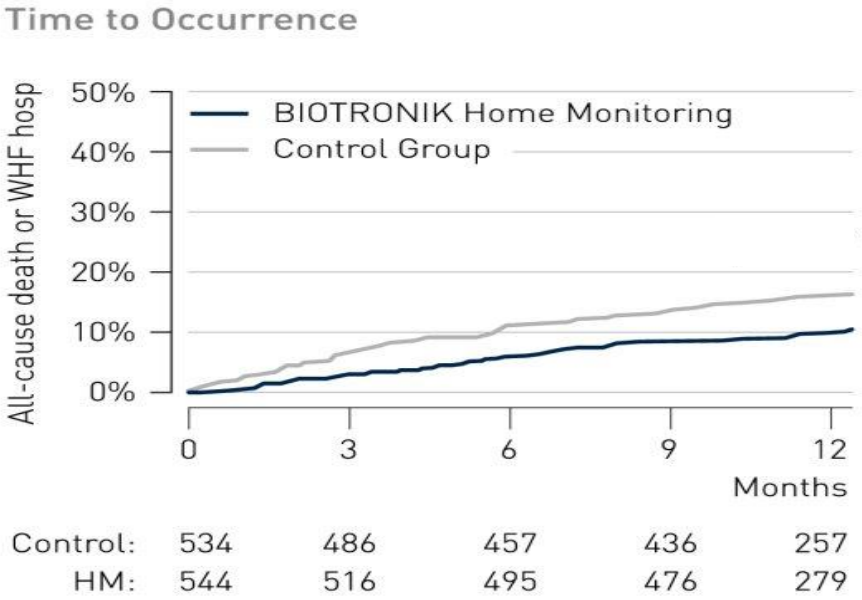
relative reduction of all-cause mortality at 1 year

Relative risk = 0.62

95% CI: 0.40 to 0.95

Hindricks G, J. Proff, N. Varma, S. Kacet, T. Lewalter, P. Sogaard, L. Guedon-Moreau, TA. Gerds, SD. Anker
Daily remote monitoring of implantable cardioverter-defibrillators: Pooled individual patient data from IN-TIME, ECOST, and TRUST trials suggest a mechanism of clinical benefit, ESC Congress 2016, Rome

Significant Reduction of All-cause Death or WHF Hospitalization with BIOTRONIK Home Monitoring



36%

relative reduction of all-cause death or WHF hospitalization at 1 year

Relative risk = 0.64

95% CI: 0.45 to 0.89

Hindricks G, J. Proff, N. Varma, S. Kacet, T. Lewalter, P. Sogaard, L. Guedon-Moreau, TA. Gerds, SD. Anker
Daily remote monitoring of implantable cardioverter-defibrillators: Pooled individual patient data from IN-TIME, ECOST, and TRUST trials suggest a mechanism of clinical benefit, ESC Congress 2016, Rome

“Prevention of Heart Failure Exacerbation” as the Main Driver for the Observed Benefits

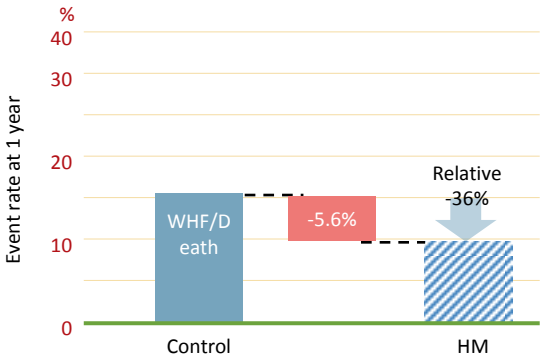
All-cause Mortality or …**WHF** hospitalization → is a subset of … **CV** hospitalization → is a subset of … **any** hospitalization

All-cause mortality or **WHF** hospitalization

Risk reduction

Absolute: -5.6% (p=0.007)

Relative: **-36%**

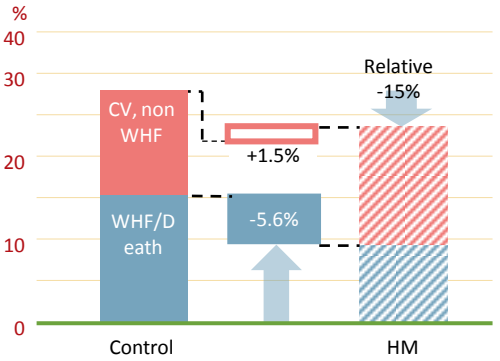


All-cause mortality or **CV** hospitalization

Risk reduction

Absolute: -4.1% (p=n.s.)

Relative: **-15%**

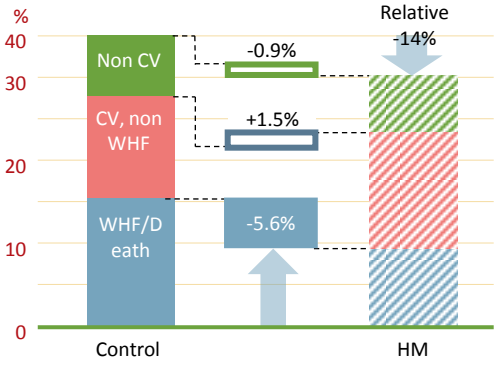


All-cause mortality or **any** hospitalization

Risk reduction

Absolute: -5.0% (p=n.s.)

Relative: **-14%**



ESC Statement 2013: Remote Monitoring Should be Considered in Order to Provide Earlier Detection of Clinical Problems

Recommendations	Class [a]	Level [b]	Ref. [c]
Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).	IIa	A	174–176

Brignole et al.; 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy; European Heart Journal, 2013:34;2281–2329-doi:10.1093/eurheartj/eht150.

HRS Statement 2015: Remote Monitoring Shall Become Standard of Care (Class 1A)

- New Class 1A recommendation for remote interrogation and monitoring of all device patients (including IPGs)
- The consensus paper highlighted also the recent findings (Varma et al. 2015) regarding the "dose dependency" of remote monitoring, i.e. the higher the transmission success the greater the survival advantage

HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A

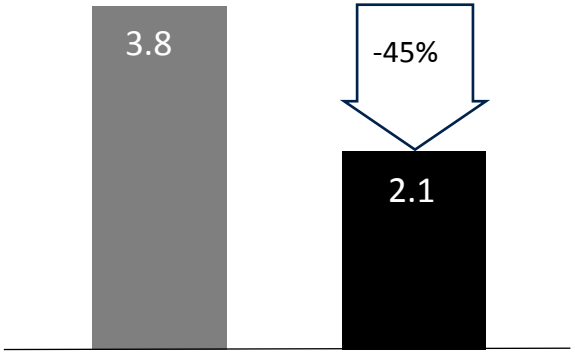
Slotwiner et al.; HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices; Heart Rhythm 2015

Objectives Remote Monitoring: 1: Improving Monitoring Efficiency

Replacing In-Office Follow-Ups While Maintaining Safety

- Several studies have shown non inferiority of Home Monitoring versus standard care
- Significant reduction of in-office follow-ups

BIOTRONIK Home Monitoring significantly reduces the number of in-office follow-ups.



Mean number of in-office follow-up visits per patient year

Varma N, Epstein A, Irimpen A, Schweikert R, Shah J, Love CJ, Investigators T. Efficacy and safety of automatic remote monitoring for ICD Follow-Up: the TRUST trial. Circulation 2010;122:325–332

Safety

- Non-inferior to conventional FU.

Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up

The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial

Niraj Varma, MA, DM, FRCP; Andrew E. Epstein, MD; Anand Irimpen, MD; Robert Schweikert, MD; Charles Love, MD; for the TRUST Investigators

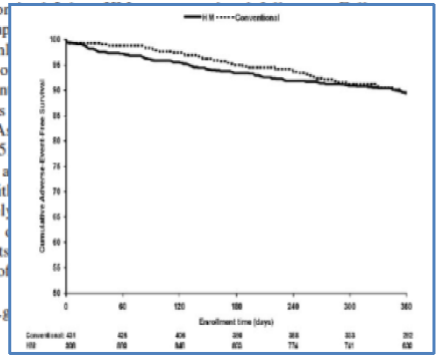
Background—Monitoring implantable cardiac device function and patient condition is important. The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) trial tested the hypothesis that remote home monitoring with automatic daily surveillance (HM) is safe and effective for implantable cardioverter-defibrillator follow-up for 1 year and enables rapid physician evaluation of significant events.

Methods and Results—In total, 1339 patients were randor checks occurred at 3, 6, 9, 12, and 15 months after imp months in the HM group. At 6, 9, and 12 months, HM onl Conventional patients were evaluated with office visits o incidence of morbidity, and time elapsed from first even tracked for each group. HM and conventional patients gender, 72.0% versus 73.1% male; New York Heart A ventricular ejection fraction, 29.0±10.7% versus 28.5 primary prevention indication, 72.2% versus 73.8%; a reduced total in-hospital device evaluations by 45% wit 6-, 9-, and 12-month follow-ups were performed remotel in the majority. Median time to evaluation was <2 conventional group ($P<0.001$) for all arrhythmic events

Conclusions—HM is safe and allows more rapid detection o in patients with implantable electronic cardiac devices.

Clinical Trials Registration—URL: http:/www.clinicaltrials.g

(***Circulation***. **2010;122:325-332.**)



A randomized trial of long-term remote monitoring of pacemaker recipients (The COMPAS trial)

Philippe Mabo[1,2,3*], Frédéric Victor[4], Patrick Bazin[5], Saïd Ahres[6], Dominique Babuty[7], Antoine Da Costa[8], Didier Binet[9], and Jean-Claude Daubert[1,2,3], on behalf of the COMPAS trial Investigators

[1]Centre Hospitalier Universitaire Pontchaillou, 2 Rue Henri Le Guilloux, Rennes 35000, France; [2]Université Rennes I, Rennes, France; [3]Unité Inserm 642, Rennes, France; [4]Polyclinique Saint Laurent, Rennes, France; [5]Centre Hospitalier de Dinan, Dinan, France; [6]Hôpital Pasteur, Colmar, France; [7]Centre Hospitalier Universitaire de Tours, Tours, France; [8]Centre Hospitalier de Saint-Etienne, Saint-Etienne, France; and [9]Hôpital Louis Pasteur, Cherbourg, France

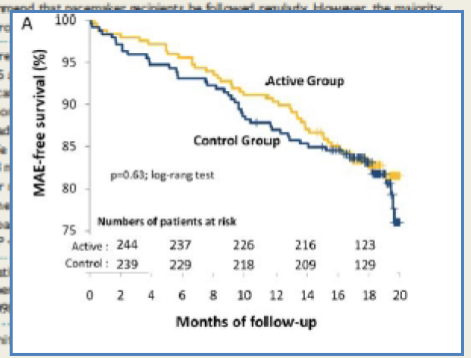
Received 7 June 2010; revised 28 September 2010; accepted 19 October 2011; online publish-ahead-of-print 29 November 2011

Aims Professional practice guidelines recommend that pacemaker recipients be followed regularly. However, the majority of scheduled ambulatory visits is unpro

Methods and results The COMPAS randomized, multicentre pacemakers. Between December 2005 follow-up (active group) vs. standard ca of patients who experienced at least o for device-related or cardiovascular ad MAE-free survivals and quality of life were similar. Over a follow-up of 18.3 m enced at least one MAE ($P < 0.01$ for (2 vs. 8) were fewer ($P < 0.05$), and the than the control group. Changes in pa active vs. 29% in the control group (P

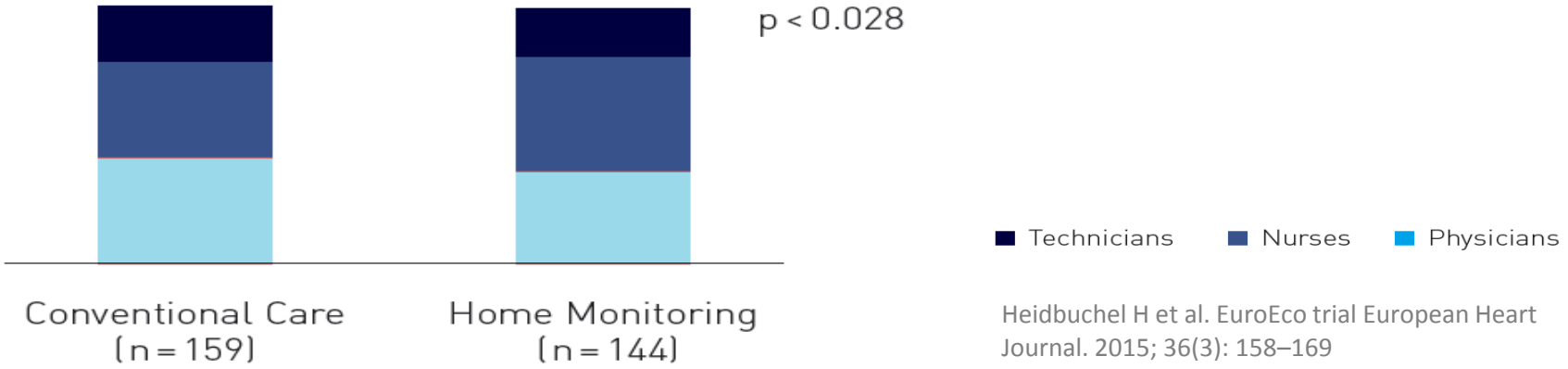
Conclusion Remote monitoring was a safe alternat visits during long-term follow-up of pe ClinicalTrials.gov identifier: NCT009

Keywords Pacemaker follow-up • Remote moni



Home Monitoring is Cost Neutral for Follow-Up Clinics

The total time needed to follow-up one ICD patient is comparable for patients monitored conventionally or with Home Monitoring (three hours over two years), but Home Monitoring reduces the necessary presence of physicians, allowing them to focus on other care activities (EuroEco RCT, n = 303)

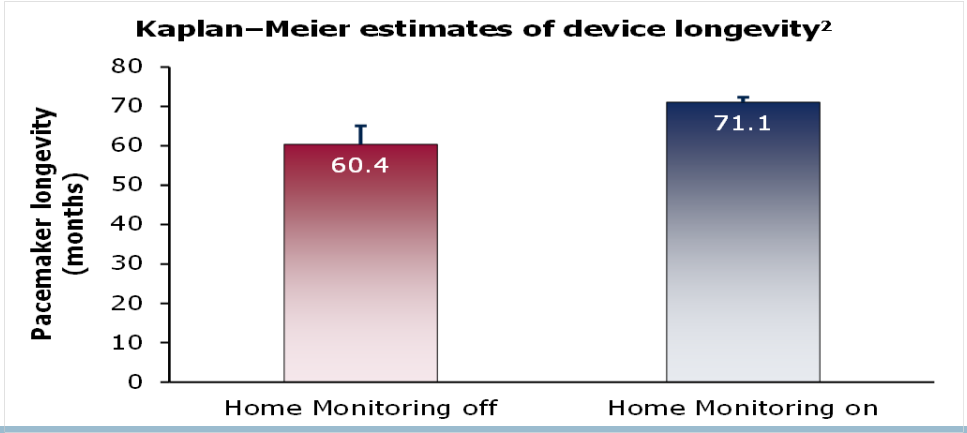


Heidbuchel H et al. EuroEco trial European Heart Journal. 2015; 36(3): 158–169

Home Monitoring extends device longevity

Extending CIED longevity is important because surgical replacement carries a risk of complications (e.g., infection, haematoma, lead dislodgement or malfunction requiring reoperation)[1]

In a retrospective analysis of 201 patients, pacemaker longevity was extended 11 months using Home Monitoring (P<0.0001)[2]

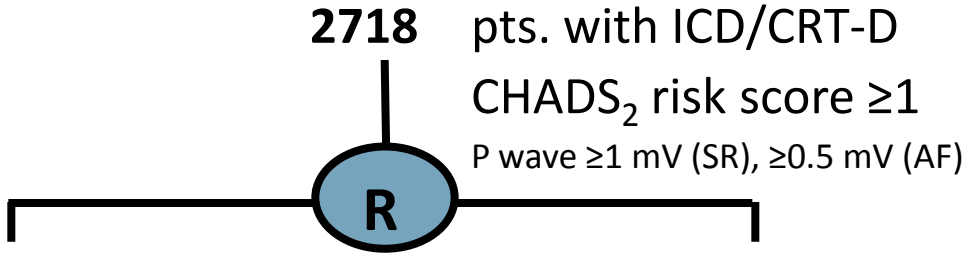


CIED: cardiovascular implantable electronic device
[1]Poole JE *et al*. *Circulation* 2010;122(16):1553-61. [2]Ricci RP *et al*. *Heart Rhythm* 2015;12(2):330-7

Reduction in Severe Adverse Events

IMPACT The Impact of Home Monitoring Guided Anticoagulation on Stroke Risk in Patients with ICD and CRT-D Devices

Recruiting



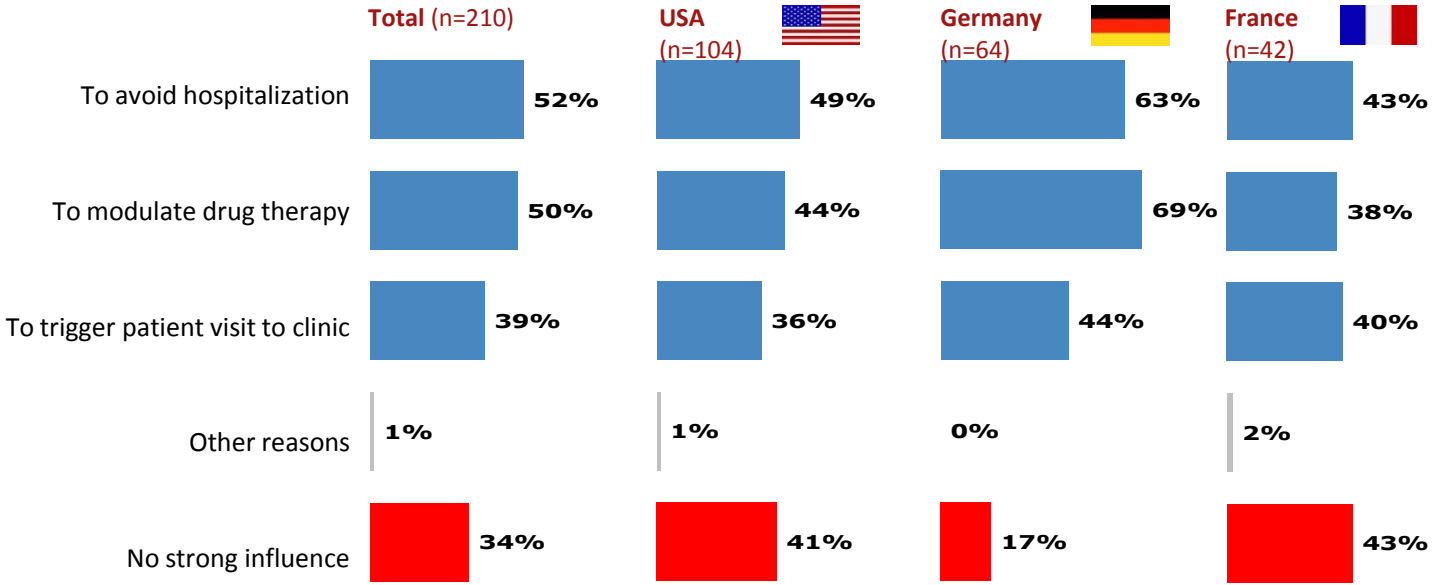
Composite endpoint: stroke, systemic embolism, major bleeding

Secondary endpoint: total mortality, stroke, bleeding, AF burden, quality of life, mean heart rate reduction

Chair: Halperin, New York/Ip, Lansing, USA
ClinicalTrials.gov

How "Heart Failure Alerts" influence a physician's decision to adopt remote TM

HF monitoring helps physician better track patient's disease



Base: All respondents
E4: You mentioned that "atrial fibrillation alerts" would have a strong influence on your decision for remote telemonitoring. Which of the following explanations apply to you?

Zdroj: Biotronik, SE

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III: Consensus opinions of professional societies (EHRA / HRS) on RC

EHRA and HRS HM Concensus Statement

ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)

Sergio Dubner[1]*, Angelo Auricchio[2], Jonathan S. Steinberg[3], Panos Vardas[4], Peter Stone[5], Josep Brugada[6], Ryszard Piotrowicz[7], David L. Hayes[8], Paulus Kirchhof[9,10], Günter Breithardt[10], Wojciech Zareba[11], Claudio Schuger[12], Mehmet K. Aktas[11], Michal Chudzik[13], Suneet Mittal[3], and Niraj Varma[14]

Document reviewers: Carsten Israel (Germany), Luigi Padeletti (Italy), and Michele Brignole (Italy)

[1]Clinica y Maternidad Suizo Argentina, Buenos Aires, Argentina; [2]Fondazione Cardiocentro Ticino, Lugano, Switzerland; [3]Valley Heart and Vascular Institute and Columbia University College of Physicians & Surgeons, New York, NY, USA; [4]Heraklion University Hospital, Crete, Greece; [5]Brigham & Women's Hospital, Boston, MA, USA; [6]Thorax Institute—Hospital Clinic, University of Barcelona, Barcelona, Spain; [7]National Institute of Cardiology, Warsaw, Poland; [8]Mayo Clinic, Rochester, MN, USA; [9]University of Birmingham Centre for Cardiovascular Sciences, Birmingham, UK; [10]Department of Cardiology and Angiology, University Hospital Münster, Münster, Germany; [11]University of Rochester, Rochester, NY, USA; [12]Henry Ford Hospital, Detroit, MI, USA; [13]Department of Electrocardiology, Medical University of Lodz, Poland; and [14]Cleveland Clinic, Cleveland, OH, USA

Received 18 August 2011; accepted after revision 19 August 2011

We are in the midst of a rapidly evolving era of technology-assisted medicine. The field of telemedicine provides the opportunity for highly individualized medical management in a way that has never been possible before. Evolving medical technologies using cardiac implantable devices (CIEDs) with capabilities for remote monitoring permit evaluation of multiple parameters of cardiovascular physiology and risk, including cardiac rhythm, device function, blood pressure values, the presence of myocardial ischaemia, and the degree of compensation of congestive heart failure. Cardiac risk, device status, and response to therapies can now be assessed with these electronic systems of detection and reporting. This document reflects the extensive experience from investigators and innovators around the world who are shaping the evolution of this rapidly expanding field, focusing in particular on implantable pacemakers (IPGs), implantable cardioverter-defibrillators (ICDs), devices for cardiac resynchronization therapy (CRT) (both, with and without defibrillation properties), loop recorders, and haemodynamic monitoring devices. This document covers the basic methodologies, guidelines for their use, experience with existing applications, and the legal and reimbursement aspects associated with their use. To adequately cover this important emerging topic, the International Society for Holter and Noninvasive Electrocardiology (ISHNE) and the European Heart Rhythm Association (EHRA) combined their expertise in this field. We hope that the development of this field can contribute to improve care of our cardiovascular patients.

Keywords Remote monitoring • Cardiovascular implantable electronic devices • Ventricular tachycardia/ventricular fibrillation

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

David Slotwiner, MD, FHRS, FACC (Chair),[1,#] Niraj Varma, MD, PhD, FRCP (Co-chair),[2,#] Joseph G. Akar, MD, PhD,[3] George Annas, JD, MPH,[4] Marianne Beardsall, MN/NP, CCDS, FHRS,[5] Richard I. Fogel, MD, FHRS,[6] Nestor O. Galizio, MD,[7*] Taya V. Glotzer, MD, FHRS, FACC,[8] Robin A. Leahy, RN, BSN, CCDS, FHRS,[9] Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,[10] Rhondalyn C. McLean, MD,[11†] Suneet Mittal, MD, FHRS,[12] Loredana Morichelli, RN, MSN,[13] Kristen K. Patton, MD,[14‡] Merritt H. Raitt, MD, FHRS,[15] Renato Pietro Ricci, MD,[13§] John Rickard, MD, MPH,[16] Mark H. Schoenfeld, MD, CCDS, FHRS, FACC, FAHA,[17] Gerald A. Serwer, MD, FHRS, FACC,[18‖] Julie Shea, MS, RNCS, FHRS, CCDS,[19] Paul Varosy, MD, FHRS, FACC, FAHA,[20] Atul Verma, MD, FHRS, FRCPC,[5] Cheuk-Man Yu, MD, FACC, FRCP, FRACP[21¶]

From the [1]Hofstra School of Medicine, North Shore - Long Island Jewish Health System, New Hyde Park, New York, [2]Cleveland Clinic, Cleveland, Ohio, [3]Yale University School of Medicine, New Haven, Connecticut, [4]Boston University School of Public Health, Boston, Massachusetts, [5]Southlake Regional Health Centre, Newmarket, Ontario, Canada, [6]St. Vincent Medical Group, Indianapolis, Indiana, [7]Favaloro Foundation University Hospital, Buenos Aires, Argentina, [8]Hackensack University Medical Center, Hackensack, New Jersey, [9]Sanger Heart & Vascular Institute, Carolinas HealthCare System, Charlotte, North Carolina, [10]New York University Langone Medical Center, New York City, New York, [11]University of Pennsylvania Health System, Philadelphia, Pennsylvania, [12]The Arrhythmia Institute at Valley Hospital, New York, New York, [13]Department of Cardiovascular Diseases, San Filippo Neri Hospital, Rome, Italy, [14]University of Washington, Seattle, Washington, [15]VA Portland Health Care System, Oregon Health & Science University, Knight Cardiovascular Institute, Portland, Oregon, [16]Johns Hopkins University, Baltimore, Maryland, [17]Yale University School of Medicine, Yale-New Haven Hospital Saint Raphael Campus, New Haven, Connecticut, [18]University of Michigan Congenital Heart Center, University of Michigan Health Center, Ann Arbor, Michigan, [19]Brigham and Women's Hospital, Boston, Massachusetts, [20]Veterans Affairs Eastern Colorado Health Care System, University of Colorado, Denver, Colorado, and [21]Department of Medicine and Therapeutics, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China.

1. Dubner S, et al. Europace 2012:14:278-293
2. Slotwiner D: http://dx.doi.org/10.1016/j.hrthm.2015.05.008

2016 ESC Heart Failure Guideline recommends multiparameter monitoring for ICD patients in order to improve clinical outcomes

European Journal of Heart Failure (2016)
doi:10.1002/ejhf.592

ESC GUIDELINES

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Developed with the special contribution of the Heart Failure Association (HFA) of the ESC

Recommendations for exercise, multidisciplinary management and monitoring of patients with heart failure

Recommendations	Class [a]	Level [b]	Ref [c]
It is recommended that regular aerobic exercise is encouraged in patients with HF to improve functional capacity and symptoms.	I	A	321, 618–621
It is recommended that regular aerobic exercise is encouraged in stable patients with HFrEF to reduce the risk of HF hospitalization.	I	A	618, 619
It is recommended that patients with HF are enrolled in a multidisciplinary care management programme to reduce the risk of HF hospitalization and mortality.	I	A	622–625
Referral to primary care for long-term follow-up may be considered for stable HF patients who are on optimal therapy to monitor for effectiveness of treatment, disease progression and patient adherence.	IIb	B	626, 627
Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMems) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF	IIb	B	628, 629
Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B	630

HF = heart failure; HFrEF = heart failure with reduced ejection fraction; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; IN-TIME = Implant-based multiparameter telemonitoring of patients with heart failure.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting levels of evidence.

Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B	630

Initial patient education

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.

Device parametrs in patient with HF

‘Vital signs’

- Weight and blood pressure (daily)

Symptoms

- Quality-of-life questions (weekly)
- Assessment of patient activity

Lead related

- Significant increase in pacing thresholds, especially the left ventricular lead
- Significant increase in the percentage of right ventricular pacing
- Significant decrease in the percentage of left ventricular pacing

Arrhythmia related

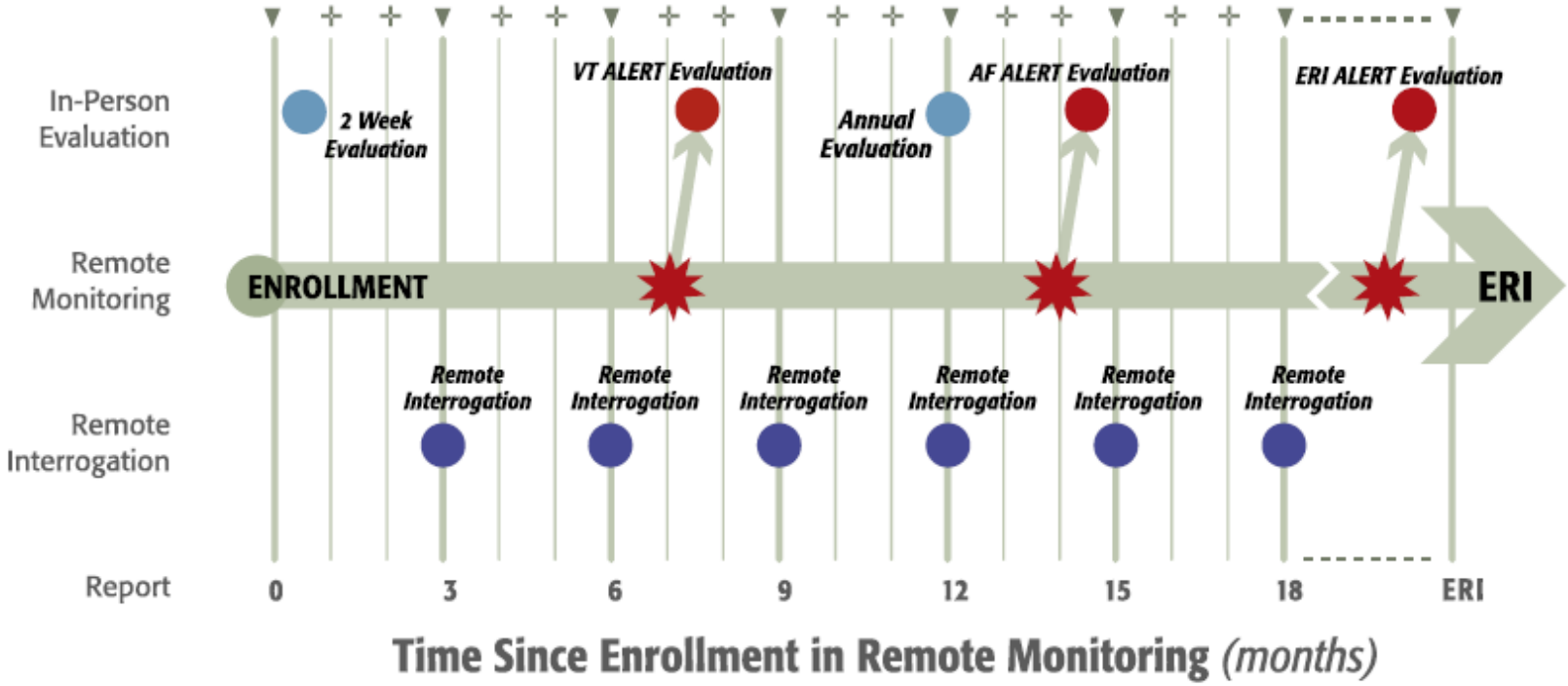
- Atrial tachyarrhythmias
- Ventricular tachyarrhythmias

Miscellaneous

- Intrathoracic impedance
- Heart rate variability
- Respiratory rate

Dubner S, et al. Europace 2012:14:278-293.

Event-based CIEDS FU



Remote Monitoring Concensus I

Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
It may be beneficial to initiate RM within the 2 weeks of CIED implantation.	IIa	C
All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up or equivalent experience.	I	E
It is recommended that RM programs develop and document appropriate policies and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.	I	E

CIED = cardiac implantable electronic device; HRS = Heart Rhythm Society; IBHRE = International Board of Heart Rhythm Examiners; IPE = in-person evaluation; RM = remote monitoring.

Remote Monitoring Concensus I

Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A
The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.	IIb	C

B-R = level of evidence B indicates a moderate level from randomized trials; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; RM = remote monitoring.

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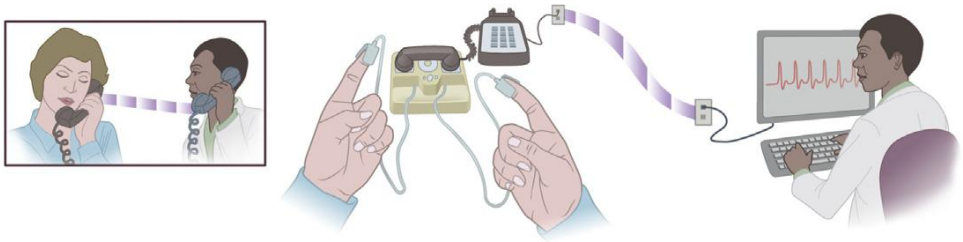
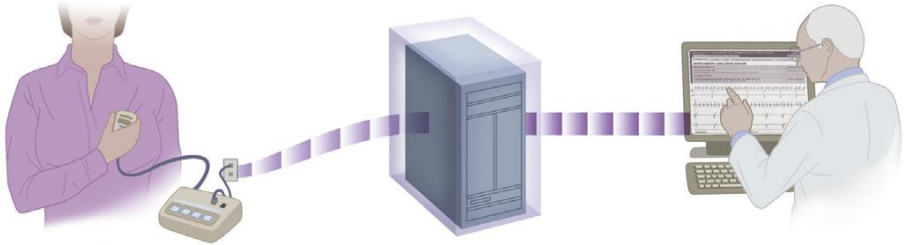
IV: Overview of RC Available Technologies 2019

RM Technologies

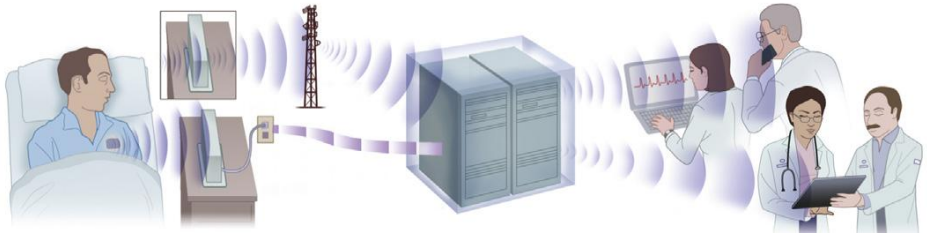
Transtelephonic



Inductive

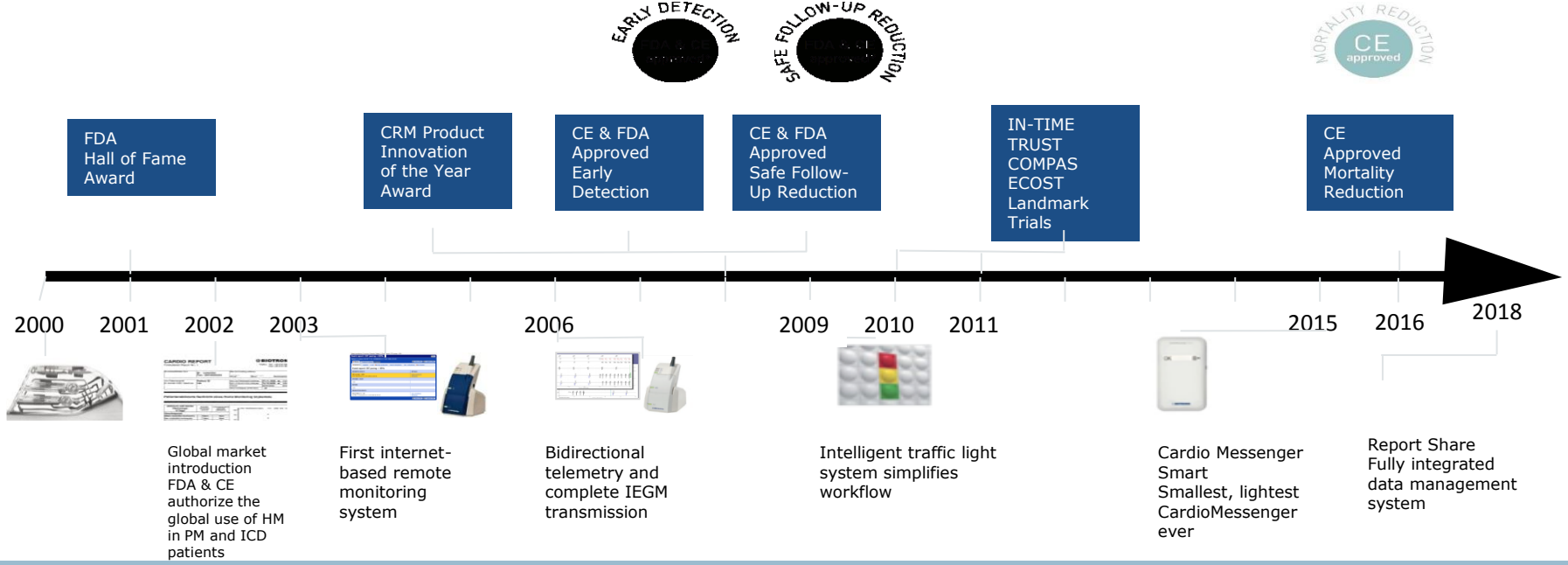


Automatic



Biotronik: History of Pioneering Innovation

Undisputed Leader in Remote Monitoring



Three key elements are needed to improve clinical outcome of HF Patients with remote monitoring

1 

Technology platform

Reliable transmission with daily verification

Implant-Based, Automatic and Daily

+

2 

Transmitted data set

Disease and patient-relevant set of rhythmological and technical parameters

Multiparametric and Relevant

+

3 

Clinical Workflow

Effective clinical workflow for fast patient contact and follow-up within two working days

Specific and Fast

Disease and patient-relevant set of rhythmological and technical parameters

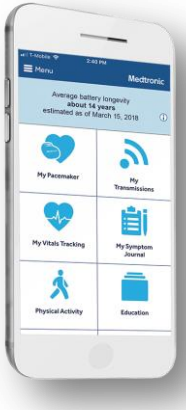
Home Monitoring Event Triggers (as used in IN-TIME)

- Mean PVC/h above limit (> 100 PVC/h)
- CRT pacing below limit (< 80%)
- Atrial monitoring episode detected
- Atrial burden above limit (> 50%)
- VT1/ VT2 and VF events
- All Technical HMSC-Findings (impedances etc.)
- No messages received for at least 3 days

MEDTRONIC: BLUESYNC™ TECHNOLOGY
APPLICATIONS

Tablet-based
SmartSync™
device manager

Azure™ Pacemaker
with BlueSyncTechnology

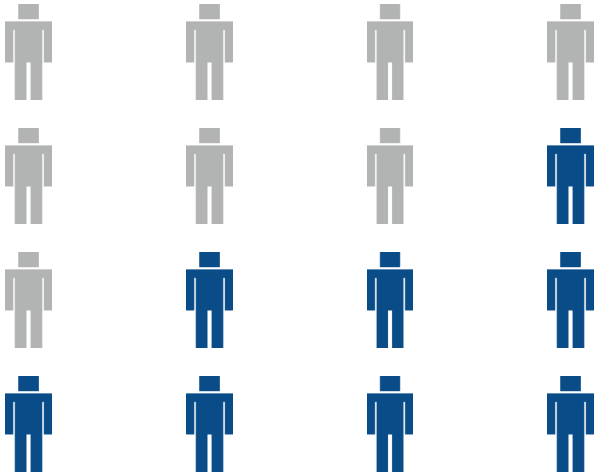


MyCareLink Heart™
Mobile App on patient's
smartphone or tablet

CareLink™ Network

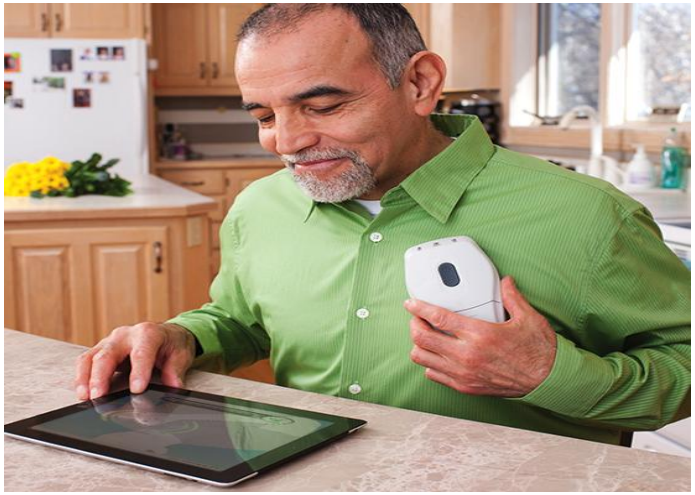
BlueSync Technology enables a connected platform that supports and engages patients throughout their healthcare journey.

Simplifies routine follow-up



Routine in-office visits may be replaced by remote visits resulting in **45% fewer**[1] in-office visits

58% less time[2] for remote vs. in-office follow-up



Remote monitoring **improves patient compliance**[1] to follow-up

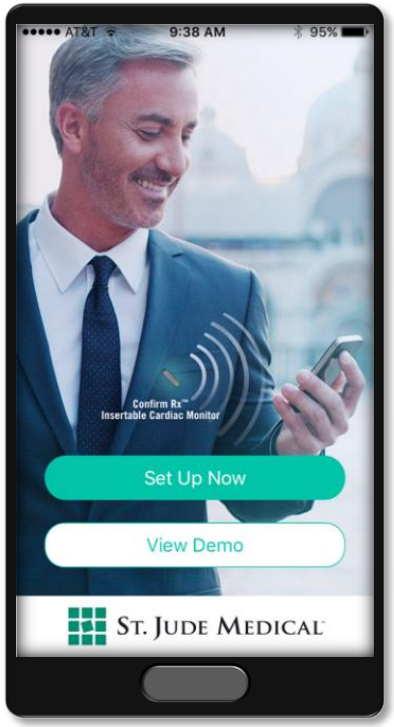
[1] Varma N. Am Heart J. 2007;154:1029-1034.

[2] Cronin EM, et al. Heart Rhythm. 2012;9:1947-1951.

Abbot/SJM: Smart Heart Monitoring via Smartphone

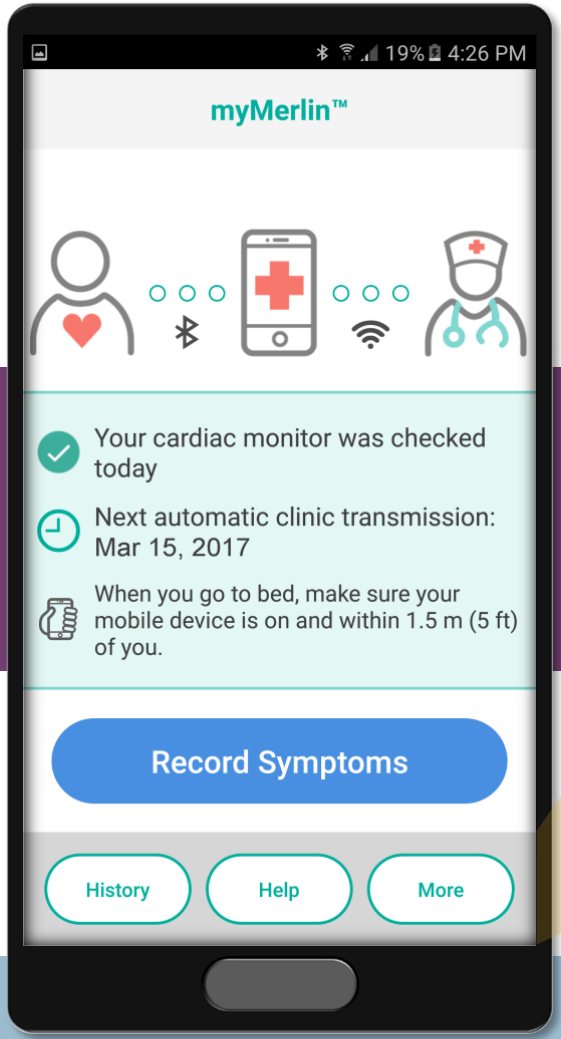
EMPOWER & ENGAGE PATIENTS with **convenient** smartphone-enabled technology and **continuous** monitoring

- Smartphone-enabled technology
- The myMerlin™ app serves as an integrated transmitter and symptom recorder
- Eliminates the need for a bulky bedside transmitter and separate activator for recording symptomatic events



ENHANCE PATIENT COMPLIANCE TO REMOTE MONITORING

via **connected** care that minimizes clinic burden



CRT-D avaible: Q4/2019

History, More, help

myMerlin™ App

Boston Scientific
Advancing science for life™

LATITUDE NXT

Simplicity, Control, Flexibility

LATITUDE NXT is compatible with Boston Scientific's wireless weight scale and blood pressure cuff

Follow the progression of HF disease with Weight Scale and BP Cuff

- Only remotely monitored diagnostic information aligned with JCAHO, ACC, AHA and **ESC guidelines** for heart failure.
- Allows you to remotely collect objective vital signs information through the **Bluetooth** enabled weight scale and blood pressure cuff.
- Patients become a part of their **own long-term care** when utilizing the external sensors.
- Patients equipped with weight scale have their device data transmitted on a weekly basis so that you always have **"fresh" data in case of weight alert**.

ELA Medical

- Bude doplněno

Výkony v souvislosti s remote control

17701 (VZP) dálková kontrola pacienta s KS/kardioverterem - první výkon 321 b

17702 (VZP) dálková kontrola pacienta s KS/kardioverterem - pravidelná kontrola 321 b

Cave: VZP x Svaz pojišťoven – pouze centra, ale ne ambulantní složka !

Přehled sledovaných pacientů v jednotlivých centrech k 8.11.2018

Homolka Praha	4
IKEM Praha	226
FNUSA Brno	103
FN Olomouc	567
FN HK	59
Pardubice	0
VFN Praha	57
Ostrava	0
FN Bohunice Brno	234
FNK. Vinohrady Praha	88
UVN Praha	11
Liberec	13
Ústí n.L.	125
Tábor	5
Bulovka	0
FN Plzeň	116
FN Motol	14
Kladno	1
Č.Budějovice	836
Kolín	0
CELKEM	**2459**

Zdroj: M. Lasota, Biotronik CZ

Take home message

1. RC does not replace the management of patient acute conditions
2. RC undoubtedly assists in the early detection of major arrhythmic changes in health
3. Properly used RC reduces rehospitalization for HF
4. The daily RC used leads to a reduction in mortality in patients with HF and CRT or ICD
5. Technologically trend to use smartphones and tablets for RC
6. Need for more complex systems for patients with HF (Bio, BSCI)
7. Real reimbursement of health insurance companies in this segment is inadequate and further intensive negotiations are needed for development into the future

Apple Heart Study

Turakhia M, Perez M, Desai M, et al.: 68th American College of Cardiology Scientific Session, New Orleans, Louisiana; March 16-18, 2019. Abstract 19-LB-20253.

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM

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I. INTERNÍ KLINIKA KARDIOLOGICKÁ
FAKULTNÍ NEMOCNICE OLOMOUC


ESC
Digital Summit
2019
5 - 6 October 2019
Tallinn, Estonia
ESC