Kardiologie Symposium
Luzern

Moderne Herzrhythmusüberwachung mit Smartphone und Apps

Corinna Brunckhorst
Universitäres Herzzentrum Zürich

7. November 2019

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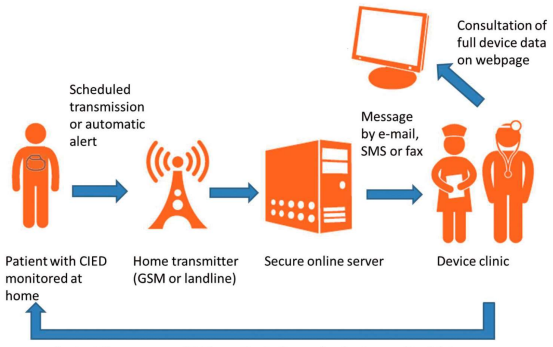
Telemedizin in der Rhythmologie

Patient	Device	Erkrankung	Informationsfluss
• Verbesserung Lebensqualität • Patienten-gerechte Device-Einstellung	• Kontrolle Device-Funktion • Identifikation Device-Probleme • Maximierung Device-Lebensdauer	• Sicherstellung der korrekten Therapie durch das Device • Dokumentation krankheits-bedingter Folgen	• Zeitnahe Patienten-information • Zeitnahe Information beteiligter Ärzte/Pflege

2

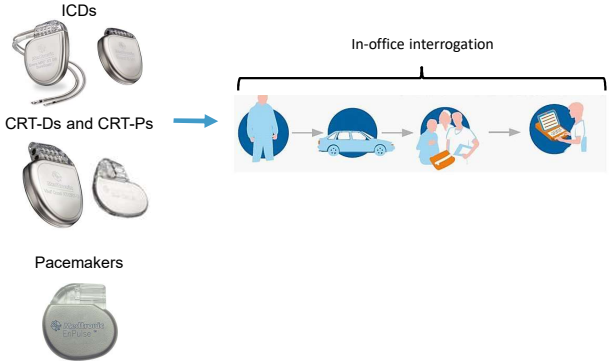
Telemedizin Setting



Burri et al. *Arrhythmia & EP* 2013; *2: 95-98*

3

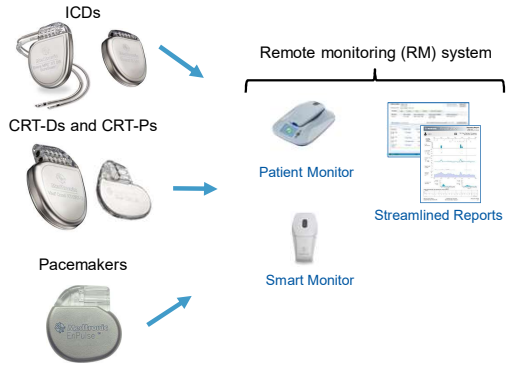
Therapeutische Devices



Taieb, J., et al. (2013). ICD in the Era of Telecardiology.

4

Telemedizin: Therapeutische Devices



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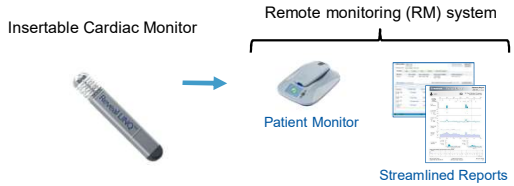
Telemedizin: Diagnostische Devices



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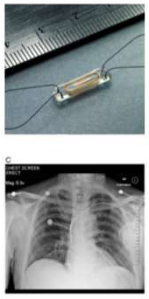
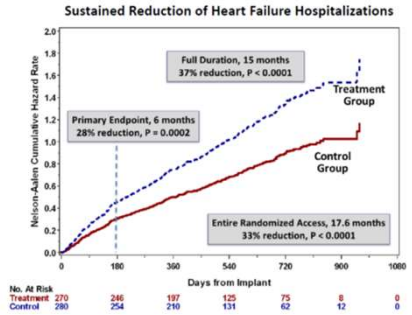
Telemedizin: Diagnostische Devices Pulmonary Artery Pressure Monitor Champion Trial

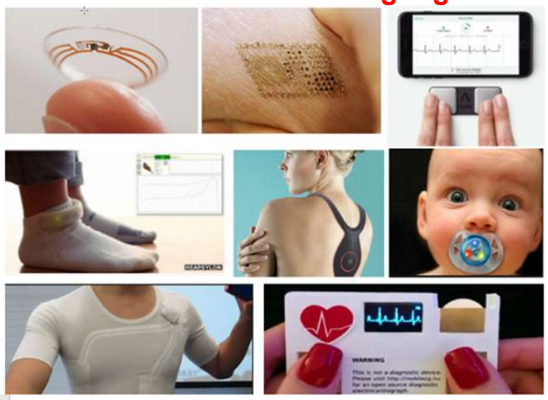




Abraham et al. Lancet 2015

7

Explosion von Monitoring Devices verschiedenster biologischer Parameter mit digitaler Analyse und Datenübertragung



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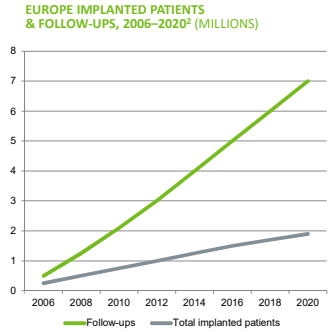
Herausforderung der Zukunft

"While there will always be more patients to manage. There will never be more time to manage them."[1]

Gimbel, 2012

As the number of patients with implants increases, so does demand for follow-ups. **How can hospitals solve this growing challenge?**



1 Gimbel, 2012, Heart Rhythm, vol 9, n°12
2 Data from projected figures modelled using 2013/14 UK CRM NICOR dataset. https://www.ucl.ac.uk/nicor/nicor-news-publication/CRM_Report_2013-14

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Internet-enabled mobile ECG (iECG)

ECG band for Apple Watch

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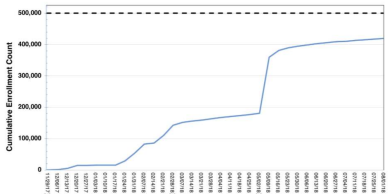
Apple's Heart Study: Technology and Work Flow

Data collected in the home setting may not have the same quality controls as data collected within a clinical trial setting. Even though, this may provide new insights into the performance and clinical outcomes associated with medical device / drug use.



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EKG-basiertes VHF Screening mit der Smartwatch-

➢ Limitationen:
- ✓ Artefakte, v.a. bei Bewegung
- ✓ Momentaufnahme
- ✓ Ungeeignet für asymptomatische Episoden und VFL Last

➢ Daher Entwicklung von kontinuierlichen PPG-basierten VHL Diagnose Algorithmen (Apple, AliveCor, HeartBeats etc.)

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Apple Watch Irregular Rhythm Notifier

- PPG-basierte Herzfrequenzmessung ca. alle 15 min.
- Jedoch nicht bei körperlicher Aktivität
- Kein FDA-approval

FDA U.S. FOOD & DRUG ADMINISTRATION

September 11, 2018

Apple Inc.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group
1555 King St, Suite 300
Alexandria, Virginia 22314

Re: DEN180042
Trade/Device Name: Irregular Rhythm Notification Feature

Page 2 - Donna-Bea Tillman DEN180042

Photoplethysmograph analysis software for over-the-counter use. A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

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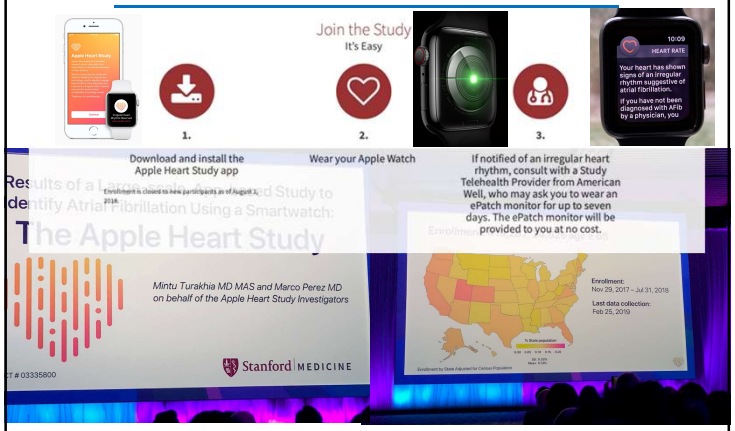
Apple Heart Study – Apple und Stanford



Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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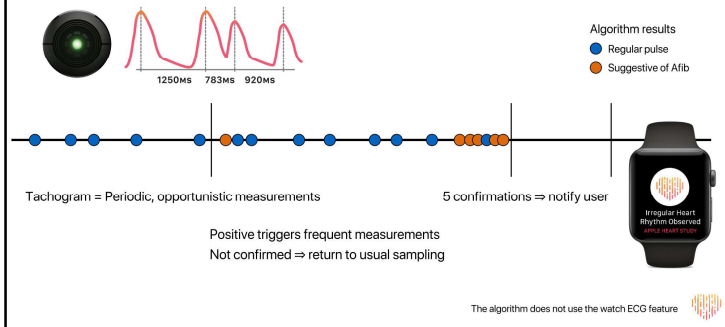
Apple Heart Study

Irregular Pulse Notification Algorithm



Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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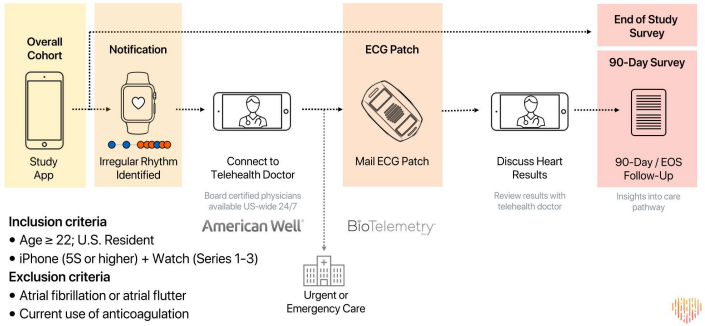
Apple Heart Study

Prospective, Single Arm, Open Label Study



Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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Apple Heart Study

	Gesamt Kohorte	Notifications	ECG Patch	VHF bestätigt
N (%)	[redacted]			
weiblich (%)				
Alter, mean (sd)	41 (13)			
>65				
55-64				
40-64				
22-39	219.179 (52)			

Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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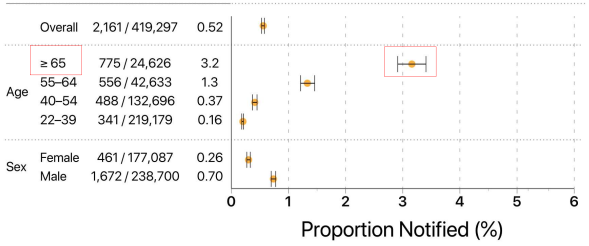
Apple Heart Study

Initial Irregular Pulse Notifications

Overall Cohort
~ 8 Months Monitoring

Grouping		Notified / Total	%
	Overall	2,161 / 419,297	0.52
Age	≥ 65	775 / 24,626	3.2
	55–64	556 / 42,633	1.3
	40–54	488 / 132,696	0.37
	22–39	341 / 219,179	0.16
Sex	Female	461 / 177,087	0.26
	Male	1,672 / 238,700	0.70



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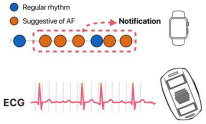
Apple Heart Study

Irregular Pulse Notifications



Afib on ECG Patch	Positive Notifications	PPV (95% CI)
72	86	0.84 (0.76–0.92)
25	32	0.78 (0.64 – 0.92)

Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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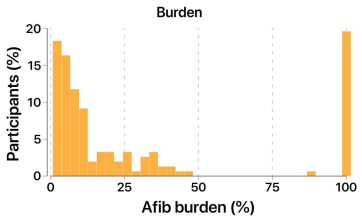
Apple Heart Study

Afib Burden and Duration

ECG Patch
153/450 With AF



Duration of Longest Episode

24 hr	25.5%
6 hr	34.0%
1 hr	29.4%
6 min	5.9%
30 sec	5.2%

89%

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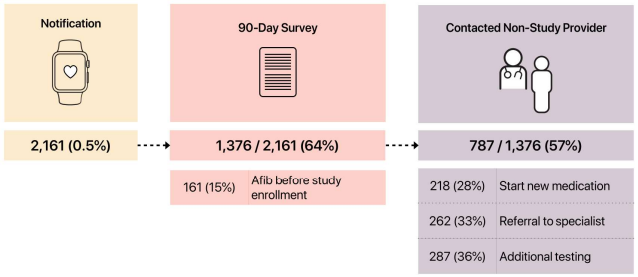
Apple Heart Study

90-Day Survey



Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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"Smartes" VHF Screening im 21. Jahrhundert...

- Single lead mobiles EKG (Abl. I) mit automatischer Analyse
- CE- und FDA-approved (iPhone und Apple Watch)
- PDF an Arzt möglich
- Von EHRA für VHF Screening empfohlen

Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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"Smartes" VHF Screening im 21. Jahrhundert...

- 3 Kategorien:
  - ✓ Unclassified
  - ✓ normal ECG
  - ✓ possible AF

Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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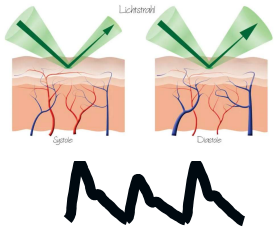
"Smartes" VHF Screening im 21. Jahrhundert...
PPG-basiert

Smartphone

Smartwatch

- Herzfrequenzbestimmung mittels Photo-Plethysmography (PPG)
- Optische Messung der Veränderung des Blutflusses
- kombiniert mit automatischer Analyse von VHF ohne EKG (Algorithmen)



Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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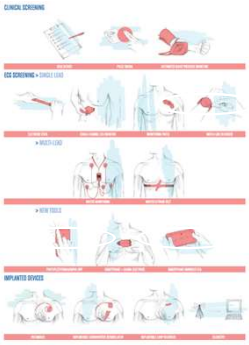
VHF Screening im Wandel… - 2017 EHRA Consensus

ESC European Society of Cardiology — EHRA CONSENSUS DOCUMENT

Screening for atrial fibrillation: a European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLAECE)



Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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Vergleich mit bestehenden Standards

	Sensitivity	Specificity
Pulse taking	87–97%	70–81%
Automated BP measurements	93–100%	86–92%
Single lead ECG screening	94–98%	76–95%
Smartphone apps	98.5%	91.4%

iPhone kombiniert mit Kardia-Band iECG

Nicht besser als automatisches Blutdruckmessgerät?

Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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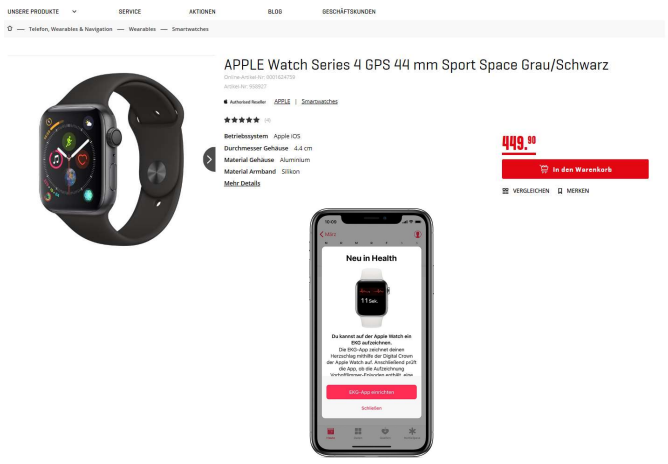
VHF Screening mit der Smartwatch



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EKG-basiertes VHF Screening mit der Smartwatch-

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Noch nicht perfekt…

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Apple Heart Study - Schlussfolgerungen

- PPV der Irregular Heart Rhythm Notification: 84%
  - ✓ bei >65j nur 78%, d.h. 22% falsch Positive
- Hoher Aufwand für relative wenig Nutzen
  - ✓ Medikationsänderung bei 0.05%
  - ✓ Keinen Einfluss auf harte Endpunkte

Mintu Turakhia, Macro Perez: Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch: The Apple Heart Study, presented at ACC 16.03.2019

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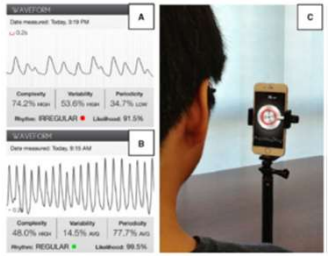
Was bringt die Zukunft?

- Neue VHF Detektions Algorithmen mit PPG und Bewegungssensoren
  - ✓Korrelation hohe Herzfrequenz mit körperlicher Aktivität (AliveCor®)
  - ✓Akkurate Detektion von VFL >1h und VFL Burden vgl. mit Reveal ILR
  - ✓PPV nur 40%
  - ✓Kontaktlose Gesichts PPG mit Smartphone Kamera (Cardiio Rhythm®)



Wasserlauf J et al. Circ Arrhythm Electrophysiol.2019;12:e0068 34. DOI: 10.1161/CIRCEP.118.006834

Yan B et al. J Am Heart Assoc. 2018;7:e008585.

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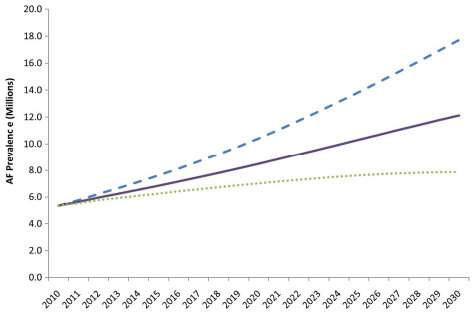
Hat Vorhofflimmern eine Bedeutung ?

- Jeder Vierte > 55 Jahre wird Vorhofflimmern entwickeln



Colilla et al. Am J Cardiol 2013; 112: 1142-1147

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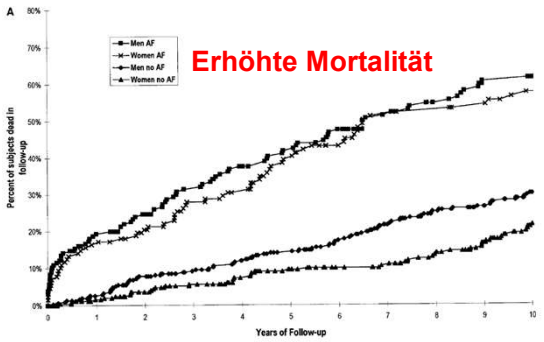
Hat Vorhofflimmern eine Bedeutung ?

USA Framingham Kohorte



Benjamin et al. Circulation 1998; 98: 946-952

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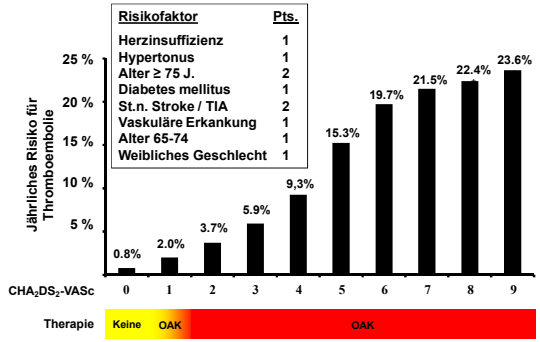
Schlaganfallrisiko bei VHF – CHA2DS2-VASc Score



P Kirchhof et al. 2016 ESC Guidelines on atrial fibrillation. Eur Heart J (2016)

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Vorhofflimmern – wieso screenen?

- Auch wenn viele Episoden asymptomatisch sind, sind sie potentiell gefährlich
- Wir können etwas tun!

P Kirchhof et al. 2016 ESC Guidelines on atrial fibrillation. Eur Heart J (2016)

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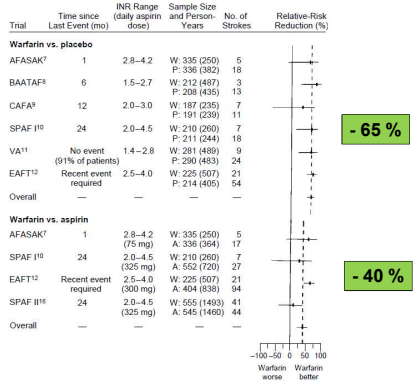
Vitamin K-Antagonisten – Standard seit 50 Jahren



Barnett et al. NEJM 1995; 332: 238-248

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NOACs vs. Warfarin

zur Schlaganfallprophylaxe

Wirkstoff	Thrombembolien	Intrakranielle Blutungen	Schwere Hämorrhagien	Mortalität
Rivaroxaban (Xarelto®)	=	↓	=	=
Apixaban (Eliquis®)	↓	↓	↓	↓
Edoxaban (Lixiana®)	=	↓	↓	↓
Dabigatran* (Pradaxa®)	↓	↓	=	=

*Hohe Dosis Dabigatran (150 mg)

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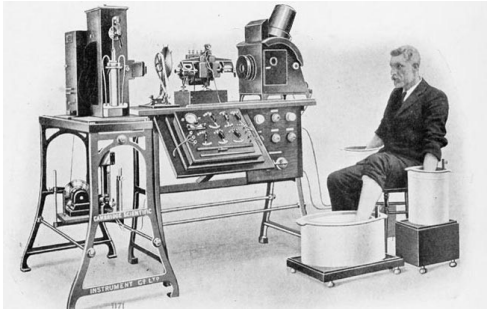
Diagnostik von Vorhofflimmern…die Anfänge



W Einthoven 1903
Nobelpreis für Physiologie

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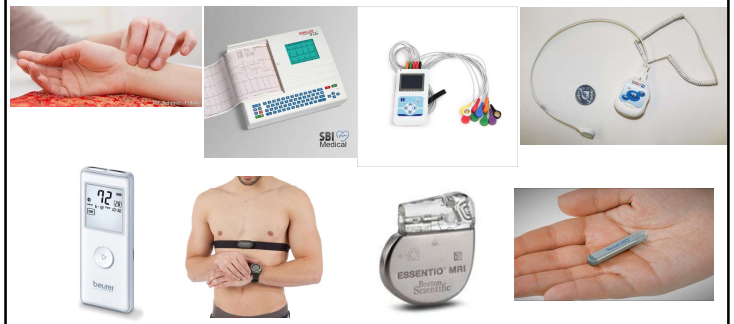
VHF Screening heute…



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VHF Screening bei kryptogenem Stroke

CRYSTAL-AF Studie

ORIGINAL ARTICLE

Cryptogenic Stroke
and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D., Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D., Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D., Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D., Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D., and Johannes Brachmann, M.D., for the CRYSTAL AF Investigators*

- Nach 12 Monaten AF bei 12.4% in ILR Arm vs. 2% in Kontrollarm
- HR 7.3; 95% CI, 2.6 to 20.8; P<0.001)

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VHF screening - 2016 ESC Leitlinien

- Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65years (Class I)
- In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72h (Class I)
- Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk (Class IIa).

P Kirchhof et al. 2016 ESC Guidelines on atrial fibrillation. Eur Heart J (2016)

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VHF Screening heute…

Bald Schnee von gestern?

- Aufwendig
- Nicht komfortabel
- Invasiv
- Teuer
- Nicht 100% perfekt

- 2/3 der Bevölkerung bei uns hat ein Smartphone (Tendenz steigend, v.a. bei >65 j)
- Immer mehr haben eine SmartWatch (ca. 6%)
- Passt zum Konzept des “Shared-decision making”

Lowres N et al. Feasibility and cost-effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH AF study. Thromb Haemost 2014;111:1167–76

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VHF Screening im Wandel… - 2017 EHRA Consensus

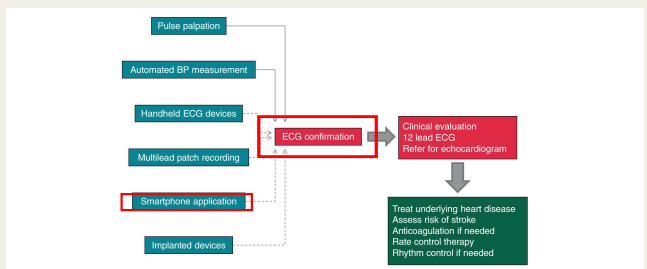

Figure 4 Screening and management strategy. BP, blood pressure; ECG, electrocardiogram.

Georges H. Mairesse: Screening for atrial fibrillation: A European Heart Rhythm Association consensus document, Europace 2017, 19, 1589-1623

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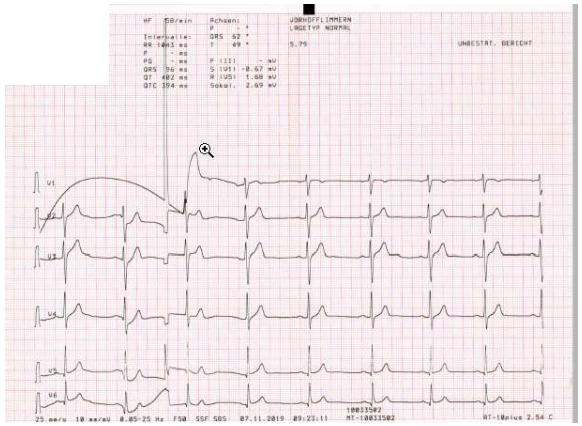

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Gefahren und offene Fragen…

- 1-Kanal EKGs und PPG Algorithmen mit Ungenauigkeiten
  - ✓ Artefakte und Fehlmessungen
  - ✓ PPG-Fehlmessungen bei sehr dunklem Hauttyp
  - ✓ Falsch Positive, z.B. Extrasystolie
- Überdiagnostik? v.a. bei Gesunden
- Wer sollte gescreent werden?
  - ✓ Möglichst viele oder weniger Probanden mit höherem Stroke Risiko
  - ✓ Kosten-Nutzen Analysen notwendig

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Gefahren und offene Fragen…

- Resourcen-> weitere unnötige Untersuchungen und Therapien
- Wer übernimmt Kosten? Krankenkassen nicht….
- Immense Datenflut
- Überprüfung durch Arzt notwendig
- In Zukunft Ablösung von Ärzten durch KI?
- Sicherheit der personenbezogenen Daten (Cybersecurity)

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Take Home Messages

- Smartwatches sind zukunftsträchtige Screening-Tools für VHF
- Selbstbestimmung und Therapieadhärenz des Patienten gestärkt
  - ✓Aber: Marktforschung: 50% aller Fitnesstracker nach einigen Monaten nicht genutzt
  - ✓Nutzen auf Gesundheit nicht belegt
- Unklar, wer und wie mit Smartwatches gescreent werden soll
- Diagnose VHF NUR mit herkömmlichen EKG, NUR durch Arzt,
- Qualität zuerst – Apps und Devices müssen zertifizierte Medizinprodukte sein

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Telemedizin
Zukunftsperspektive

1. Telemedizin hat bereits den medizinischen Alltag verändert
2. Telemedizin wird ein wichtiger Teil der Medizin der Zukunft sein
3. Künstliche Intelligenz wird bei der Datenverarbeitung eine Rolle spielen?!

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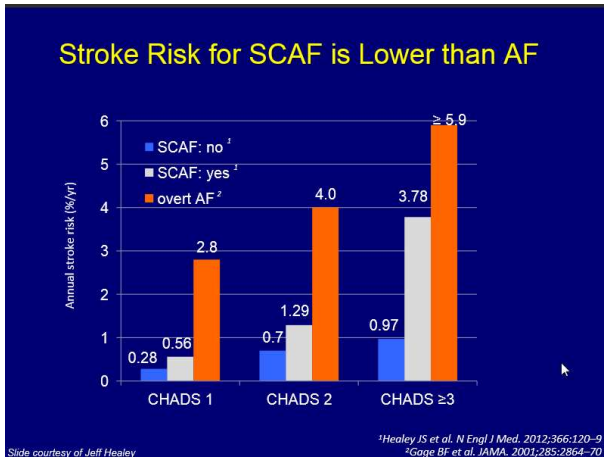
Stroke Risk for SCAF is Lower than AF



Slide courtesy of Jeff Healey

¹Healey JS et al. N Engl J Med. 2012;366:120–9
²Gage BF et al. JAMA. 2001;285:2864–70

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HRS Consensus Statement on Cardiac Device Remote Monitoring

"Wireless remote monitoring has fundamentally changed the paradigm of how we care for patients with cardiovascular implantable electronic devices. **Randomized clinical trials have demonstrated that remote monitoring is superior** to a calendar-based schedule of periodic in-person device interrogations. Yet the rate of **adoption of the technology into clinical practice has varied widely."**[1]

LOCAL REIMBURSEMENT OFTEN DOES NOT CONFORM TO THIS STATEMENT, MEANING HOSPITALS ARE LESS INSENTIVISED TO ADOPT REMOTE MONITORING

2015 Consensus Statement: Remote Interrogation & Monitoring of Cardiovascular Implantable Electronic Devices

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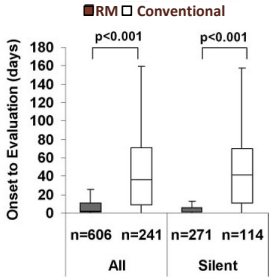
Zeitverlust: Detektion bis Evaluation

Median time from clinical event to evaluation[1]



RM results in a substantial decreases in the time to detection/evaluation of clinical events

- **TRUST Trial (ICD patients)**[1]
  - 94% reduction in time from a clinical event to evaluation
- **CONNECT Trial (ICD/CRT-D patients)** [2]
  - 79% reduction in time from a clinical event to a clinical decision
- **MORE-CARE (CRT-D patients)** [3]
  - Clinical decisions were made 93% faster

1. *Circ Arrhythm Electrophysiol.* 2010;122:325-332.
2. *J Am Coll Cardiol.* 2011;57:1181-1189.
3. *J Med Internet Res.* 2013;15(8):e167.

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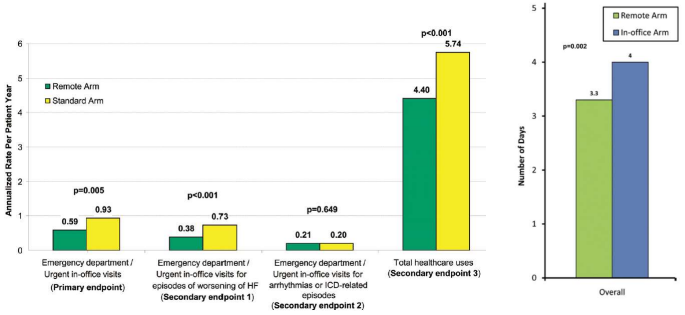
Klinische Vorstellungen und Hospitalisationsdauer

In the EVOLVO trial, heart failure patients with an ICD or CRT-D had decreased emergency/urgent visits and total healthcare utilizations when followed by RM



Landolina et al. *Circulation* 2012; 125: 2985-2992
Crossley et al. *JACC* 2011; 57: 1181-1189

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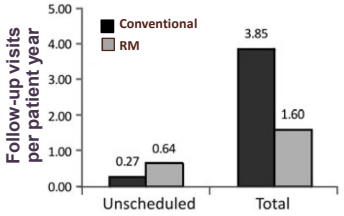
Klinische Vorstellungen

RM decreases the total number of in-person follow-up visits without compromising safety

- 58% reduction in REFORM Trial (ICD patients)[1]
- 45% reduction from TRUST trial (ICD patients)[2]
- 56% reduction in COMPAS Trial (pacemaker patients) [3]
- 24% reduction in ECOST Trial (ICD patients) [4]

Mean number of follow-up visits per patient-year[1]



1. Eur Heart J. 2014;35:98–105.
2. Circulation. 2010;122:325-332.
3. Eur Heart J. 2012;33:1105–1111.
4. Eur Heart J. 2013;34: 605–614.

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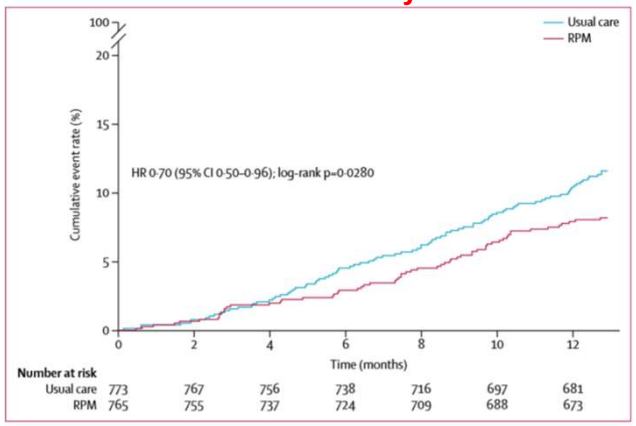
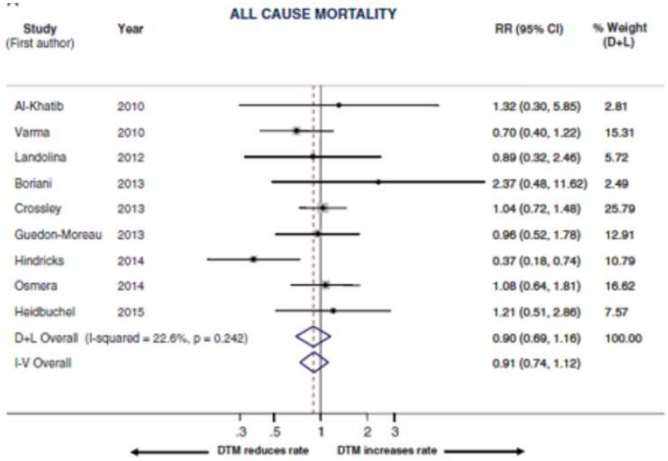
TIM-HF2 Study



Köhler F et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial; Lancet 2018

55



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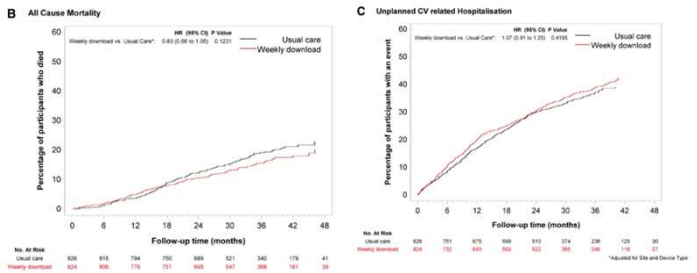
REM-HF Study



Morgan et al. Eur Heart J 2017

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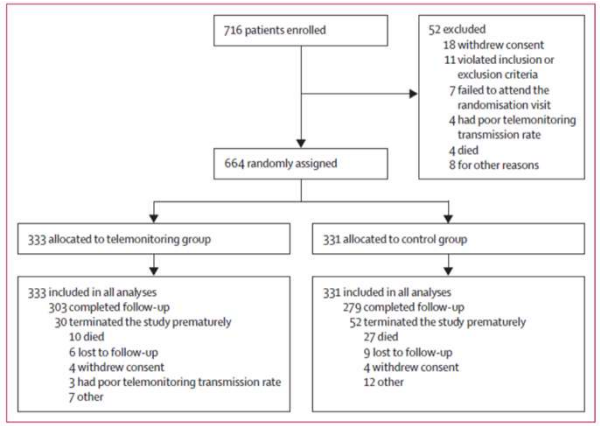
In-Time Study



Hindricks et al. Lancet 2014

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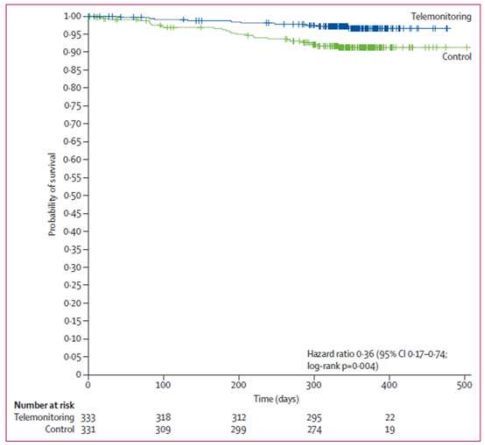
In-Time Study



Hindricks et al. Lancet 2014

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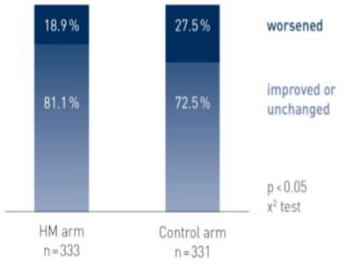
At study end, a patient is classified "worsened" in case of

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



Hindricks et al. Lancet 2014

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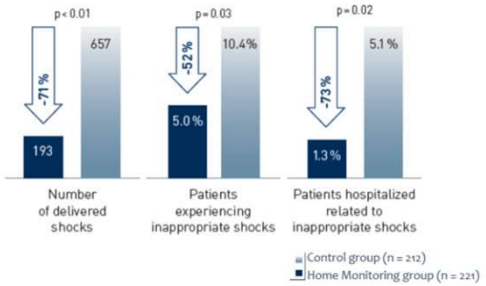
ECOST Study
Reduction of Appropriate and Inappropriate Shocks



Guedon-Moreau et al. Eur Heart J 2012

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European Heart Journal (2017) 38, 1749–1755
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]

	TRUST[3]	ECOST[5]	IN-TIME[12]
No. of centres	102 USA sites	43 French sites	26 German sites, 10 sites elsewhere[a]
Patient eligibility	Class1 indication for ICD, not pacemaker dependent	Indication for ICD, not NYHA class IV	Indication for ICD or CRT-D, heart failure (≥ 3 months), NYHA class II or III, LVEF ≤ 35%
Primary objective	To evaluate safety and efficacy of extended IO intervals	To compare major CVAEs including all-cause death	To compare heart failure outcomes using composite ("Packer") score[b]
Follow-up schedule			
HM group	IO at 3M and 15M. HM replaced IO at 6M, 9M, and 12M	IO at 1-3M, 15M, and 27M. HM replaced IO at 9M and 21M	IO at 12M, and in-between according to hospital routine
Control group	IO every 3M	IO at 1-3M, then every 6M	Same as in the HM group
Blinded endpoint committee	No	Yes	Yes

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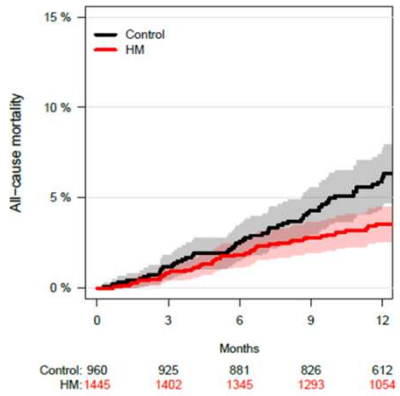
Meta-Analysis von In-TIME, TRUST und ECOST



p=0.037

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	Biotronik Home Monitoring™	Medtronic CareLink™	Boston Scientific Latitude™	Sorin SMARTVIEW™	St Jude Merlin.net™
Wireless communication with implanted device	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency
Data transmission	GSM network	Analogue phoneline and GSM network	Analogue phoneline	Analogue or GSM	Analogue or GSM
Transmitter	Mobile or stationary (GSM)	Stationary	Stationary	Stationary	Stationary
Frequency of transmissions	Scheduled FU; daily FU; alert events	Scheduled FU; alert events; on patient demand	Scheduled FU; alert events	Scheduled FU; alert events	Scheduled FU; alert events
Remote CIED control	Yes	Yes	Yes	Yes	Yes
Remote monitoring	Yes	Yes	Yes	Yes	Yes
Physician notification	SMS, email, fax	SMS, email	Fax, phone	Fax, email, SMS	Fax, email, SMS
Feedback to patient via transmitter	LED indicating normal status or call to clinic	Confirmation for successful interrogation and transmission	Automatic text and audio messages	LED indicating HM status	LED indicating call to clinic, automated phone calls
IEGM (real-time at remote follow-up)	30 s (monthly periodic EGMs)	10 s	10 s	7 s	30 s
IEGM (arrhythmic episodes)	45 sec (30 pre trigger 15 pre conclusion)	All memorized episodes	All memorized episodes	All memorized episodes	All memorized episodes
FDA and CE Mark system approval	Yes	Yes	Yes	No	Yes

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	Biotronik Home Monitoring℠	Medtronic CareLink™	Boston Scientific Latitude™	Sorin SMARTVIEW™	St Jude Merlin.net™
FDA and CE Mark for early detection	Yes	No	No	No	No
FDA and CE Mark for safe Fup reduction	Yes	No	No	No	No
Authomatic Thresholds	Automatic RA, RV and LV thresholds.	Automatic RA, RV, and LV (Consulta and Protecta XT) pacing thresholds			Automatic RA, RV, and LV pacing thresholds (next generation of ICDs)
Heart Failure Monitor	Comprehensive heart failure monitor (9 parameters), intrathoracic impedance measurement	Comprehensive heart failure monitor (4 parameters +Cardiac Compass), Optivol® lung fluid status alert	Optional wireless weight scales and BP cuffs	SMARTVIEW HF featuring PhD clinical status	CoRVUE fluid status alert
"Traffic light" system	Configurable red and yellow alerts	Configurable red and yellow alerts	Configurable red and yellow alerts		
Additional Features	Alerts fully configurable online. Patient callback	ILR RM Patient initiated transmissions Access for heart failure specialists and general cardiologist.	Configurable data transmission to associated caregivers	Patient initiated transmissions Access for heart failure specialists and general cardiologist	Alerts fully configurable online Send phone calls to pats.
Report Export	Electronic health record export compatibility	PDF export of patient reports	Electronic health record data export capability	PDF export of patient reports	
RM Compatible Devices	Devices available for RM	Any already implanted devices available for RM			

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Kosteneffizienz?

Einsparungen:

1. Weniger Fahrtkosten
2. Weniger Patientenvorstellungen
3. Erhöhte Effizienz bei Patientenvorstellungen

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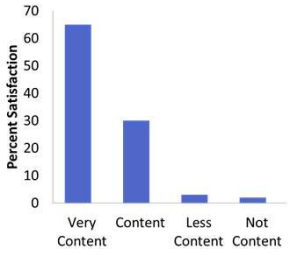
Patienten Zufriedenheit

Multiple studies have demonstrated high patient satisfaction with RM

- Peterson et al. (ICD/CRT-D patients) [1]
  - 95% of patients followed remotely were content or very content
  -
- Ricci et al. (pacemaker and ICD patients)[2]
  - 95% had a favorable opinion of RM
  - 97% would continue with RM
- Morichelli et al. (ICD/CRT-D patients) [3]
  - 99% of patients had favorable responses to RM
- Raatikainen et al. (ICD patients)[4]
  - >90% of patients thought their RM system was easy to use

Patientenzufriedenheit bei RM[1]



1. J Interv Card Electrophysiol. 2012;34:317–324.
2. Europace. 2010;12:674–679.
3. J Interv Card Electrophysiol. 2014;41:203–209.
4. Europace. 2008;10:1145–1151.

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Robuste Evidenz

- Reduced in-hosp visits
  - REFORM
  - TRUST
- As safe
  - REFORM
  - TRUST
  - ECOST
- Increased QofL
  - REFORM
- Reduced shocks
  - ECOST
- Earlier notification
  - TRUST

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HRS Guidelines

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
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.

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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Telemedizin: Diagnostische Devices

ICMs have been shown to:

- Improve diagnostic yield in unexplained syncope
  - 33-78% improvement over conventional methods
- Improve detection of asymptomatic and intermittent AF
  - Cryptogenic stroke
    - Use of ICM provides superior diagnostic yield than conventional monitoring
  - Post-ablation
    - Improved detection of AF

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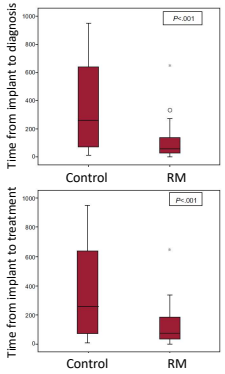
Synkope: Schnellere Diagnosestellung und Therapiebeginn



- Velu et al. (patients with unexplained syncope)[1]
  - 47% reduction in mean time from ICM implant to diagnosis
- Drak-Hernandez et al. (patients with unexplained syncope or palpitations)[2]
  - RM increased:
    - The time from implant to diagnosis by 78%
    - The time from implant to treatment by 72%
- Furukawa et al. (patients with unexplained syncope or palpitations)[3]
  - RM decreased the mean time to first relevant ECG by ~71 days

1. *Europace.* 2010;4 (suppl 4):iv22-iv27.
2. *Rev Esp Cardiol.* 2013;66(12):943–948.
3. Europace. 2011;13:431–437.

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ESC European Society of Cardiology

European Heart Journal (2018) 00, 1–69
doi:10.1093/eurheartj/ehy037

ESC GUIDELINES

2018 ESC Guidelines for the diagnosis and management of syncope

The Task Force for the diagnosis and management of syncope of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)

Endorsed by: European Academy of Neurology (EAN), European Federation of Autonomic Societies (EFAS), European Federation of Internal Medicine (EFIM), European Union Geriatric Medicine Society (EUGMS), European Society of Emergency Medicine (EuSEM)

Authors/Task Force Members: Michele Brignole* (Chairperson) (Italy), Angel Moya* (Co-chairperson) (Spain), Frederik J. de Lange (The Netherlands), Jean-Claude Deharo (France), Perry M. Elliott (UK), Alessandra Fanciulli (Austria), Artur Fedorowski (Sweden), Raffaello Furlan (Italy), Rose Anne Kenny (Ireland), Alfonso Martín (Spain), Vincent Probst (France), Matthew J. Reed (UK), Ciara P. Rice (Ireland), Richard Sutton (Monaco), Andrea Ungar (Italy), and J. Gert van Dijk (The Netherlands)

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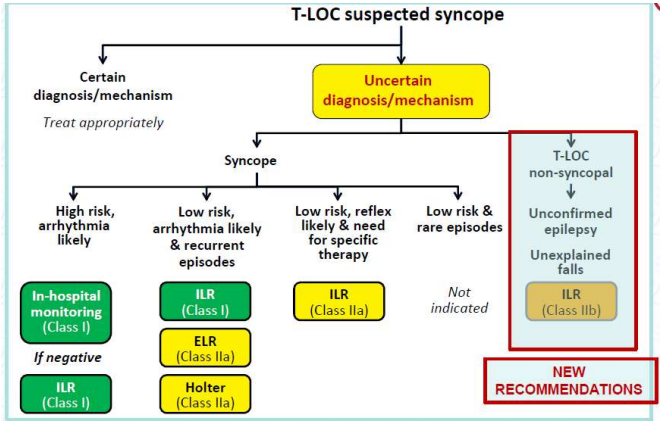
ECG Monitoring Indications



ESC Guidelines 2018

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Kontinuierliches AF Monitoring

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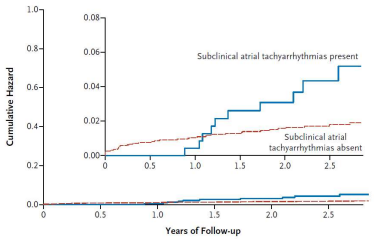
ASSERT: Subclinical AF

- 2,580 pts. with a history of hypertension, ≥65 years, no history of AF and not on OAC received a DDD / ICD (ASSERT)
- Pts. with AT (A rate >190 for more than 6 min) during a 3 months period (10.1%) had a 2.5 higher risk of ischemic stroke or systemic embolism
- Clinical AF was only detected in 15.7% of these pts.

Risk of ischemic stroke or systemic embolism



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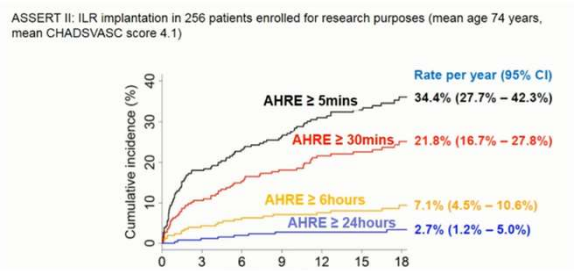
ASSERT II: AHRE sind häufig



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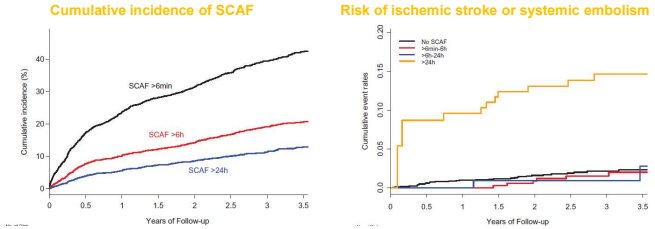
ASSERT: AF Duration and Stroke

- 2,580 pts. with a history of hypertension, ≥65 years, no history of AF and not on OAC received a DDD / ICD (ASSERT)
- Subclinical AF (SCAF) longer than 24h was associated with an increased risk of ischemic stroke / systemic embolism



Van Gelder I. *European Heart Journal* 2017; 38: 1339–1344

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Atrial fibrillation requires diagnosis by ECG I

ESC European Society of Cardiology

The diagnosis of AF requires rhythm documentation using an electrocardiogram (ECG) showing the typical pattern of AF: Absolutely irregular RR intervals and no discernible, distinct P waves. ECG-documented AF was the entry criterion in trials forming the evidence for these guidelines. By accepted convention, an episode lasting at least 30 s is diagnostic.

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Vorteile der Telemedizin:

EVIDENZ VON IMPLANTIERTEN DIAGNOSTISCHEN DEVICES

1. RM: zusätzliches diagnostisches Tool bei Synkopenabklärung
2. RM: Ggf. zusätzliches diagnostisches Tool bei Vorhofflimmern Diagnostik

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Vorteile der Telemedizin:

EVIDENZ VON IMPLANTIERTEN THERAPEUTISCHEN DEVICES

1. Frühere Detektion und Evaluation klinischer und device-bezogener Events
2. Weniger Patientenvorstellungen bei gleicher Sicherheit
3. Weniger Hospitalisationen
4. Kürzerer Spitalaufenthalt
5. Bessere Kosteneffizienz
6. Hohe Patientenzufriedenheit
7. Geringere Mortalität im follow-up

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Telemedizin: Risiken und offene Fragen

1. Cave: Pseudosicherheit!
2. Datenanalyse allein verbessert nichts!

   → entscheidend ist die Umsetzung in therapeutische Konsequenzen

3. Verschiedene Systeme verschiedener Hersteller
4. Bisher keine Schnittstelle zwischen RM und Spitalsystemen
5. Datenexplosion in der Zukunft

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