Implantable Loop Recorder (ILR) Technology update

Dr Blandine Mondésert
Electrophysiology service, Medicine department
Adult Congenital Heart Disease Center
Montreal Heart Institute
Université de Montréal

DISCLOSURES

- Grants/Research Support:
  - ✓ Boston Scientific

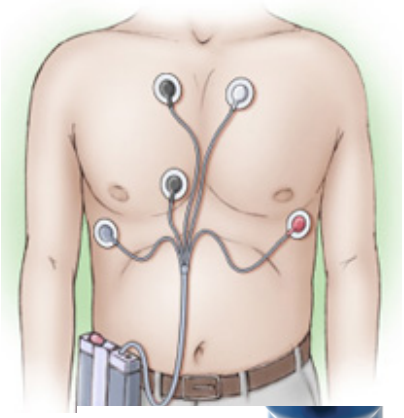
- Speakers Bureau/Honoraria:
  - ✓ Boston Scientific
  - ✓ Medtronic
  - ✓ S^{t} Jude Medical

ILR

- Syncope
- Atrial Fibrillation
- Cryptogenic stroke (ESUS)

ECG MONITORING

24-Hour Holter	~7 Day Event Recorder	14-30 Day "MCOT"	Insertable Cardiac Monitor



INSTITUT DE CARDIOLOGIE DE MONTRÉAL

AF diagnosis

- 24h-Holter ECG: 2-6%

Ziegler PD, Heart Rhythm 2006
Lazzaro MA, J Stroke Cerebrovasc Dis 2012

- 30d-Monitoring: 0-24%

Elijovich L, J Stroke Cerebrovasc Dis 2009
Gaillard N, Neurology 2010
Bhatt A, Stroke Res treat 2011
Flint AC, Stroke 2012

- Insertable Cardiac Monitor (ICM): 16-33.7%

Glotzer TV, Heart Rhythm 2015
Ritter MA, Stroke 2013
Cotter PE, Neurology 2013

EVOLUTION OF REVEAL™ ILR

1998	2014	2017
World's first ILR	World's smallest ICM	TruRhythm™ Detection
Reveal™ ILR	Reveal LINQ™ ICM	intelligence inside the Reveal LINQ™ ICM
		

ACCURACY EVOLUTION

2009

Reveal™ XT

AF Industry's first AF detection algorithm

2011

Reveal™ XT

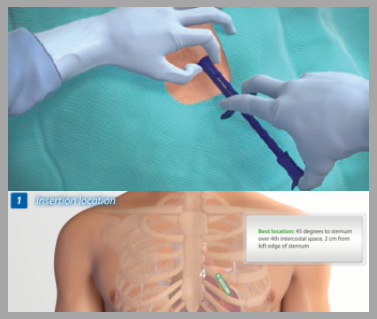
With FullView ™ Software

PAUSE Pause algorithm with diminishing R-wave analysis

AF AF algorithm and improved noise discrimination

2014

Reveal LINQ™



Simplified insertion and tight pocket for better signal

AF AF algorithm with increased accuracy

2017

TruRhythm™ Detection

Streamlined episode review for clinic efficiency[1,2]

Algorithms with
- Smart filtering
- Self-learning intelligence

BRADY PAUSE AF

---

[1] TruRhythm™ Detection Efficiency. Medtronic data on file. 2017
[2] TruRhythm™ Detection Algorithms. Medtronic data on file. 2017

NEW ALGORITHMS REVEAL LINQ

SMART FILTERING

Second sensing filter analyzes rhythms for possible undersensing in Brady and Pause

BRAD & PAUSE

SELF-LEARNING

Exclusive fifth-generation atrial fibrillation algorithm **learns and adapts** to patient's rhythm over time

AF

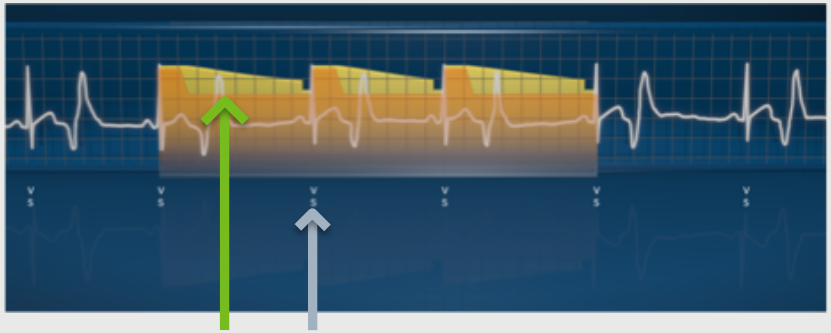
SMART FILTERING ALGORITHM

Exclusive second filter rejects Brady and Pause episodes with:

BRADY & PAUSE

EVIDENCE OF PVCs

PVCs example

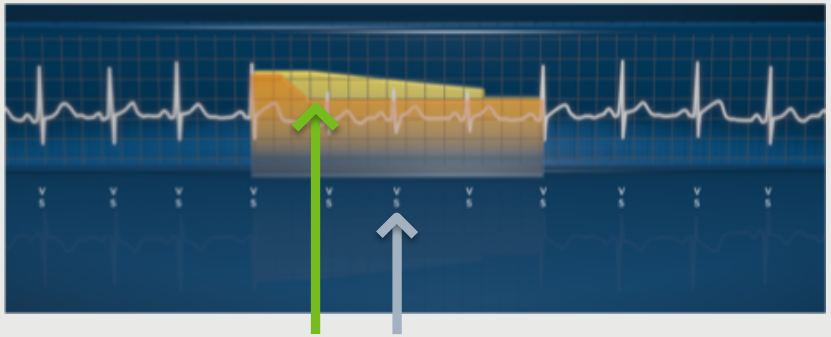


Above image: Threshold of new, second filter detects PVCs

Result: ECG markers re-classified; false episodes rejected

EVIDENCE OF SMALL R-WAVES

Small R-waves example

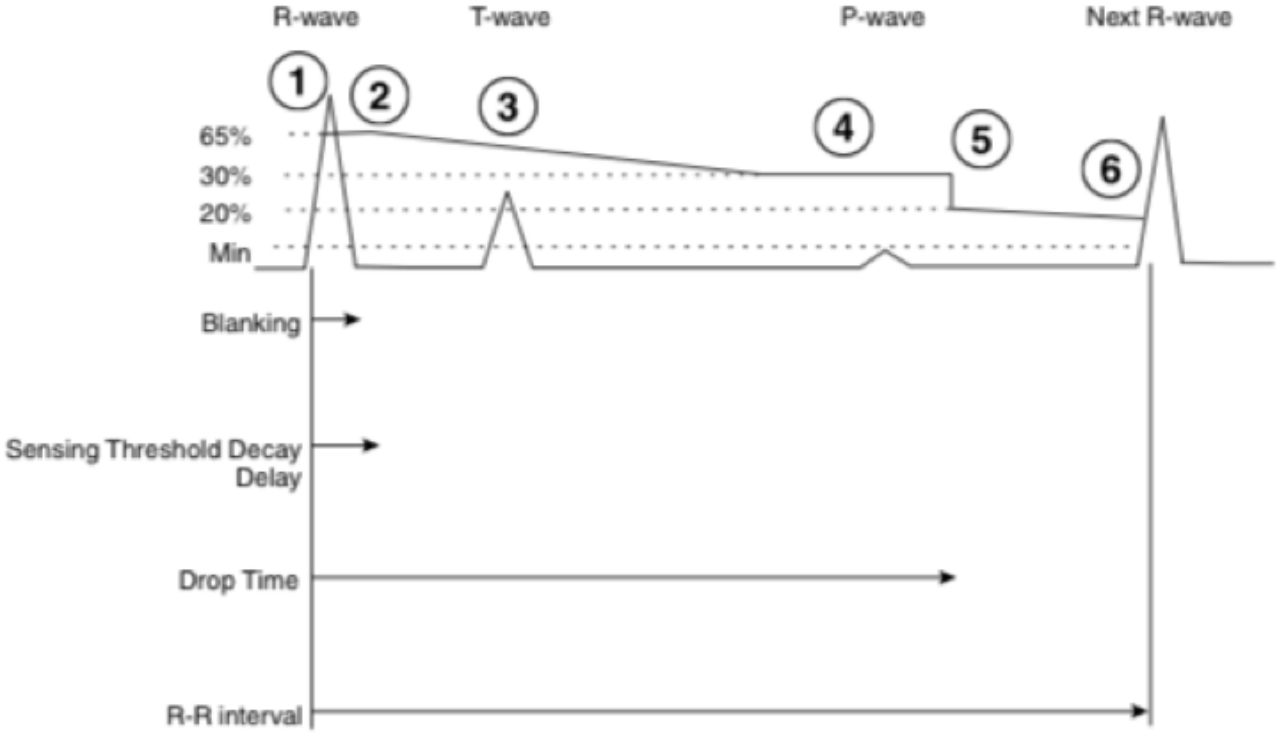


Above image: Threshold of new, second filter detects small R-waves

Result: ECG markers re-classified; false episodes rejected

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Figure 27. Auto-adjusting the sensing threshold



1 After a sensed R-wave, a programmable blanking period is started and the sensing threshold is set to 65% of the ECG peak.

2 The sensing threshold stays at this level during the programmable Sensing Threshold Decay Delay period.

3 After the Sensing Threshold Decay Delay period is finished, the sensing threshold decreases to 30% of the ECG peak within 1 s.

4 The sensing threshold stays at this level until 1.5 s has elapsed since the R-wave was sensed.

5 The sensing threshold then drops to 20% of the ECG peak.

6 The sensing threshold continues to decrease until a new R-wave is sensed or the minimum threshold is reached. The minimum threshold is the programmed sensitivity setting.

AF EPISODES

Further enhance current AF algorithm to improve AF discrimination in patients with **irregular sinus arrhythmias** (sick sinus or PACs)

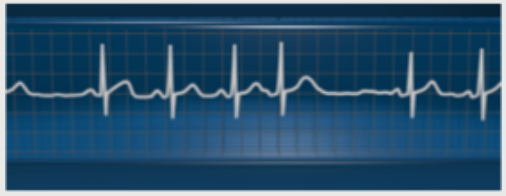
AF

CHALLENGE YESTERDAY

Algorithm cannot adapt based on a patient's history

AF detection algorithms based on R-wave variability alone inappropriately detect sick sinus or PACs

The Reveal LINQ™ ICM's **P-Sense algorithm** uniquely identifies P-waves and rejects false AF episodes



P-Sense sometimes cannot identify P-waves in patients with irregular sinus rhythms

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

SELF-LEARNING ALGORITHM

Exclusive fifth-generation AF algorithm **learns and adapts** to a patient's daily rhythm

AF

1. LEARNS

AF algorithm tracks R-wave variability in a patient and keeps their P-wave evidence history

2. ADAPTS

Self-learning algorithm collects P-wave evidence for a patient and adapts

3. REJECTS

Self-learning algorithm rejects false AF in patients with irregular sinus

Université de Montréal

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

MORE ACTIONABLE AF REPORTS

- 30 seconds of ECG for longest AF episodes
- 2 minutes of markers of longest AF episode

AF episodes will show **30 seconds of ECG**
vs.
10 seconds, from wireless transmissions

AF episodes will have **~2 minutes of intervals**
vs.
10 seconds, from wireless transmissions

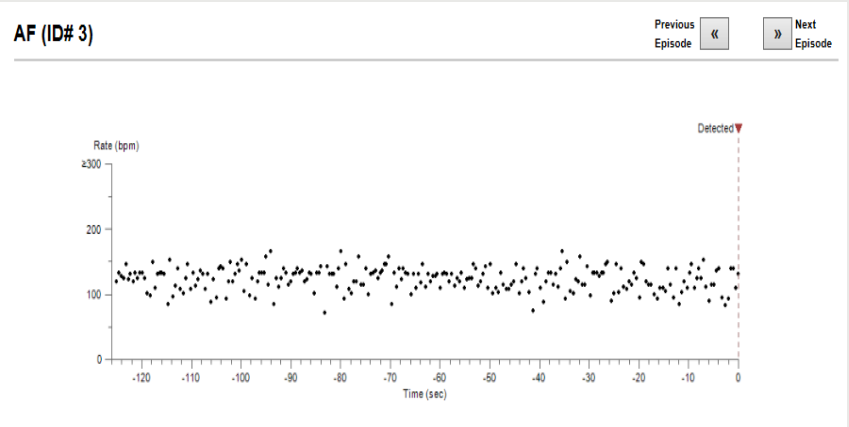


Table 5. Programmable parameters: Device Data Collection

Parameter	Programmable values	Shipped value	Reset value
Reason for Monitoring[a]	Syncope; Palpitations; Seizures; Ventricular Tachycardia; Suspected AF; AF Ablation; AF Management; Cryptogenic Stroke; Other◈	—	—
Device Date/Time…[b]	(Enter current date and time)	—	1 Jan 1994
Wireless Transmission Time…[c]	00:00◈; 01:00; 02:00 … 11:00; 12:00; 13:00 … 23:00	00:00 (midnight)	00:00 (midnight)
Wireless Data Priority	Brady, Tachy, Pause; Brady, Pause, Tachy; Tachy, Brady, Pause; Tachy, Pause, Brady; Pause, Tachy, Brady; Pause, Brady, Tachy	Pause, Tachy, Brady	Pause, Tachy, Brady
Device Data Collection[d]	On◈	Off	On

[a] Reason for Monitoring is used to set arrhythmia detection parameters to pending automatically.
[b] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.
[c] Wireless Transmission Time programming is based on the Device Date/Time clock.
[d] Turning on Device Data Collection enables sensing and data collection (all episode types). After being turned on, Device Data Collection cannot be turned off.

Université de Montréal

Table 6. Programmable parameters: R-wave sensing

Parameter	Programmable values	Shipped value	Reset value
Sensitivity	0.025; 0.035◈; 0.05; 0.075; 0.1; … 0.2 mV	0.035 mV	0.035 mV
Blank after Sense	130; 150◈; 170; 200; 250; 300; 400 ms	150 ms	150 ms
Sensing Threshold Decay Delay	130; 150◈; 200; 300; 400; 500 ms	150 ms	150 ms

Table 8. Programmable parameters: Symptomatic Episode Duration

Parameter	Programmable values	Shipped/Nominal/Reset value
Symptomatic Episode Duration	Four 7.5 min Episodes◈; Three 10 min Episodes; Two 15 min Episodes	Four 7.5 min Episodes

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Table 7. Programmable parameters: episode detection

Parameter	Programmable values	Shipped value	Reset value
Tachy Detection	On; Off	Off	On
Tachy Detection Interval (Rate)	270; 280; … 520 ms 222; 214; … 115 bpm	340 ms 176 bpm	340 ms 176 bpm
Tachy Duration	5; 12; 16^; 24; 32; 48 beats	16 beats	16 beats
Brady Detection	On; Off	Off	On
Brady Interval (Rate)	1000; 1200; 1500; 2000^ ms 60; 50; 40; 30^ bpm	2000 ms 30 bpm	2000 ms 30 bpm
Brady Duration	4^; 8; 12 beats	4 beats	4 beats
Pause[a] Detection	On; Off	Off	On
Pause[a] Duration	1.5; 3.0^; 4.5 s	3.0 s	3.0 s
AT/AF Detection	On; Off	Off	On
Type	AT/AF; AF Only	—	AF Only
AF Detection	Least Sensitive; Less Sensitive; Balanced Sensitivity; More Sensitive	Less Sensitive	Less Sensitive
Ectopy Rejection	Off; Nominal; Aggressive	Off	Off
AT/AF Recording Threshold	All Episodes; ≥6 min; ≥10 min; ≥20 min; ≥30 min; ≥60 min; Only Longest Episode	≥10 min	≥10 min
Detect Very Regular AT Rhythms	Off; On - Rates ≥67 bpm; On - Rates ≥100 bpm; On - All Rates	Off	—

[a] Asystole.

Table 9. Parameters set to pending automatically according to the selected Reason for Monitoring the patient

Reason for Monitoring[ab]	AF detection sensitivity[c]	Ectopy rejection[c]	AT/AF recording threshold[c]	Wireless data priority[c]
Syncope	Least Sensitive	Aggressive	Only Longest Episode	Pause, Tachy, Brady
Palpitations	Less Sensitive	Nominal	Episodes ≥6 min	Tachy, Pause, Brady
Seizures	Least Sensitive	Aggressive	Episodes ≥10 min	Pause, Tachy, Brady

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Table 9. Parameters set to pending automatically according to the selected Reason for Monitoring the patient (continued)

Reason for Monitoring[ab]	AF detection sensitivity[c]	Ectopy rejection[c]	AT/AF recording threshold[c]	Wireless data priority[c]
Ventricular Tachycardia	Least Sensitive	Aggressive	Episodes ≥10 min	Tachy, Pause, Brady
Suspected AF	Less Sensitive	Nominal	Episodes ≥6 min	Tachy, Pause, Brady
AF Ablation	Balanced Sensitivity	Nominal	All Episodes	Tachy, Pause, Brady
AF Management	Balanced Sensitivity	Nominal	All Episodes	Tachy, Pause, Brady
Cryptogenic Stroke	Balanced Sensitivity	Aggressive	All Episodes	Tachy, Pause, Brady
Other[n]	Less Sensitive	Aggressive	Episodes ≥10 min	Pause, Tachy, Brady

[a] For all Reasons for Monitoring, Tachy Detection Interval is programmed automatically to the closest value less than or equal to 230 bpm minus the patient's age, as calculated from the information entered in Patient Date of Birth.

[b] For all Reasons for Monitoring, AT/AF Detection Type is set to AF Only.

[c] AF detection sensitivity, Ectopy rejection, AT/AF recording threshold, and Wireless data priority parameters are set to pending automatically according to the selected Reason for Monitoring.

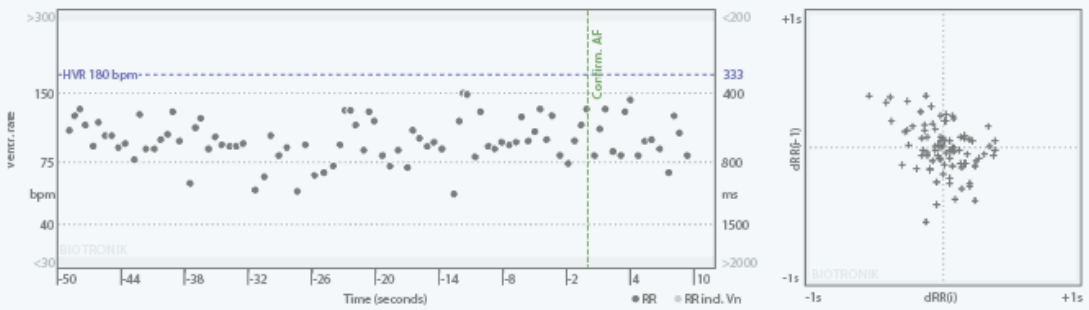
BIOMONITOR 2

Full Body Approved

3.0 T Approved

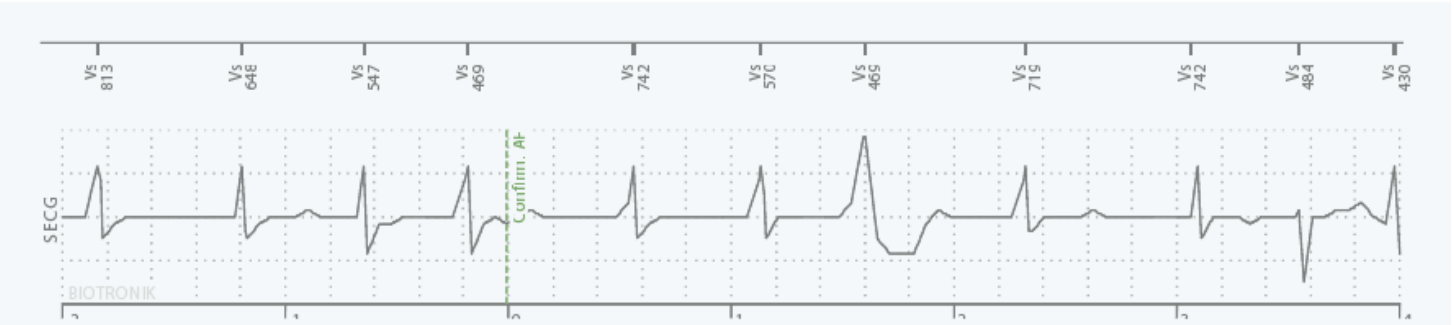
INSTITUT DE CARDIOLOGIE DE MONTRÉAL

BIOMONITOR 2



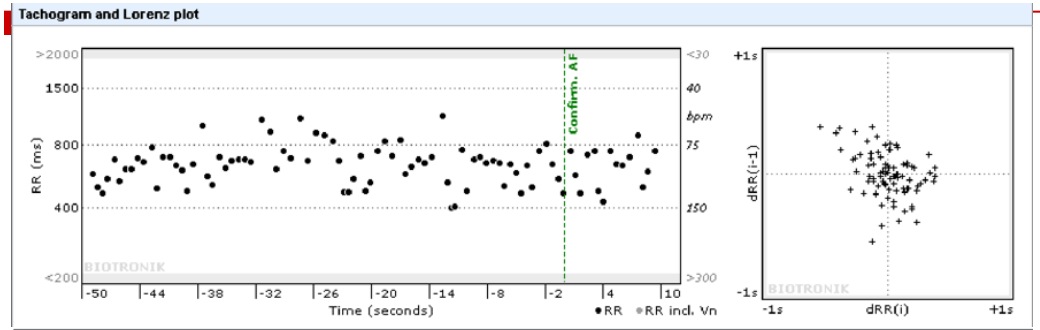
Tachogram

Lorenz plot

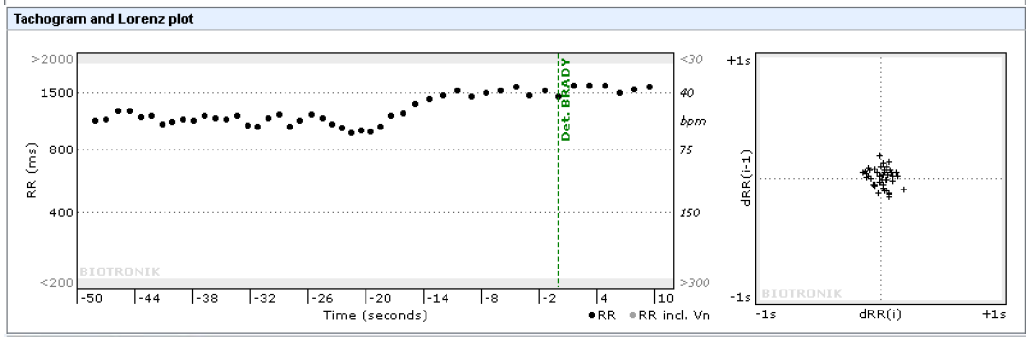


SECG

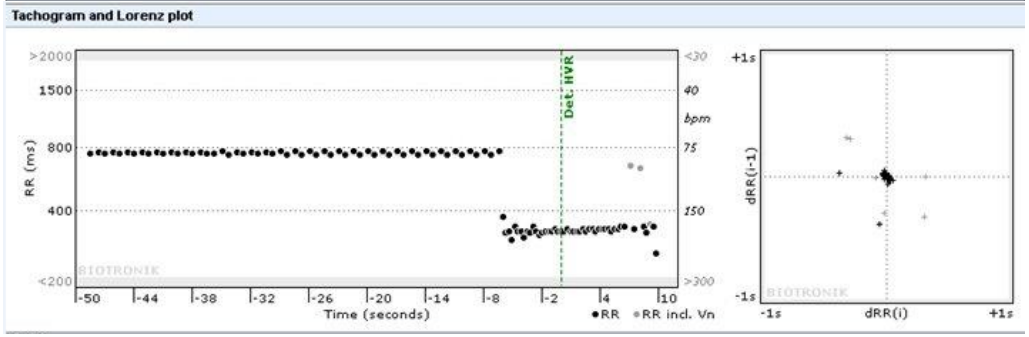
BIOMONITOR 2



AF



Bradycardia



High Ventricular Rate

Université de Montréal

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

High Sensing Quality

High R-wave amplitude

Up to **1.7 mV**

1st clinical experience in Australia (30 patients) showed R-wave amplitudes of up to 1.7 mV after insertion and also at 1-month follow-up)

BIOMONITOR 2

- 60 min
  - ✓ Automatically 55*40sec (30 sec before, 10 sec after)
  - ✓ Pt activated 4 episodes 7.5 min (7 min before, 30 sec after)
- 6 triggers
  - ✓ AF
  - ✓ Bradycardia
  - ✓ Sudden Rate Drop
  - ✓ Asystole
  - ✓ High Ventricular Rate (HVR)
  - ✓ Patient trigger

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Atrial fibrillation detection settings

Valid for BioMonitor 2-AF, the following can be set:

Parameter	Range of values	Standard	Factory
Atrial fibrillation (AF)	ON; OFF	ON	OFF
AF sensitivity	Low; Medium; High In case of change of the AF expert parameters: Individual	Medium	Medium

Additional AF expert parameters can be set individually:

Parameter	Range of values	Standard	Factory
RR variability limit	6.25; 12.5; 18.75	12.5% (medium)	
Onset/resolution window	8/16; 16/24; 24/32	8/16 cycles (medium)	
Onset intervals	5 ... (2) ... 23	5 cycles (medium)	
Resolution intervals	1 ... (2) ... 7	1 cycle (medium)	
Confirmation time	1 ... (1) ... 6; 10; 20; 30	6 min (medium)	
Bigeminy rejection	OFF; Standard; Aggressive	Standard (medium)	

The AF expert parameters are preset as follows:

Parameter	Low	Medium	High
RR variability limit	18.75%	12.5%	6.25%
Onset/resolution window	16/24 cycles	8/16 cycles	8/16 cycles
Onset intervals	9 cycles	5 cycles	5 cycles
Resolution intervals	3 cycles	1 cycle	1 cycle
Confirmation time	6 min	6 min	6 min
Bigeminy rejection	Standard	Standard	Standard

Sudden rate drop

The following can be set:

Parameter	Range of values	Standard	Factory
Sudden rate drop (SRD)	OFF; Rate decrease: 20 ... (10) ... 70%	OFF	OFF
SRD sensitivity	Low; Medium; High In case of change of the SRD expert parameters: Individual	Medium	Medium

Additional SRD expert parameters can be set:

Parameter	Range of values	Standard	Factory
Baseline intervals	48; 64; 128; 256	64 cycles (medium)	
Rate-drop intervals	8; 16; 32	16 cycles (medium)	

The SRD expert parameters are preset as follows:

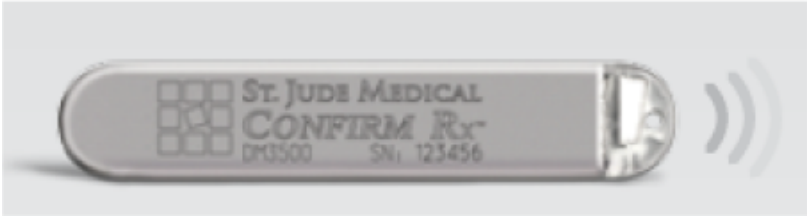
Parameter	Low	Medium	High
Baseline intervals	256 cycles	64 cycles	48 cycles
Rate-drop intervals	32 cycles	16 cycles	8 cycles

Asystole duration

The following can be set:

Parameter	Range of values	Standard	Factory
Asystole duration	OFF; 2 ... (1) ... 10	3 s	OFF

CONFIRM RX



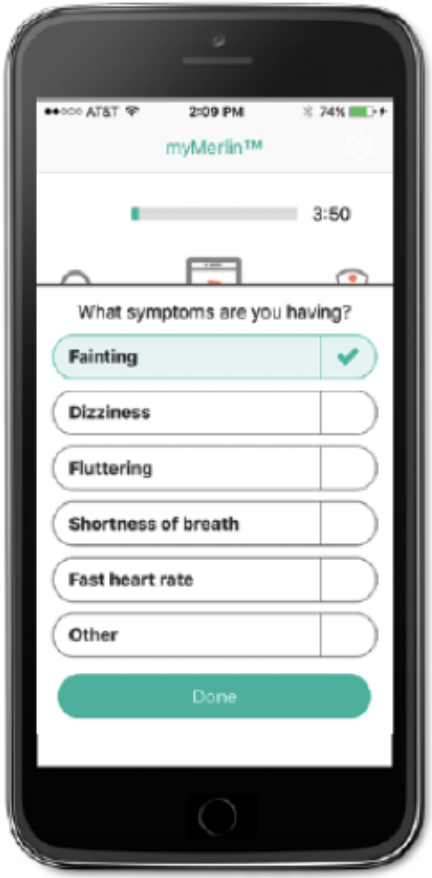
Université de Montréal

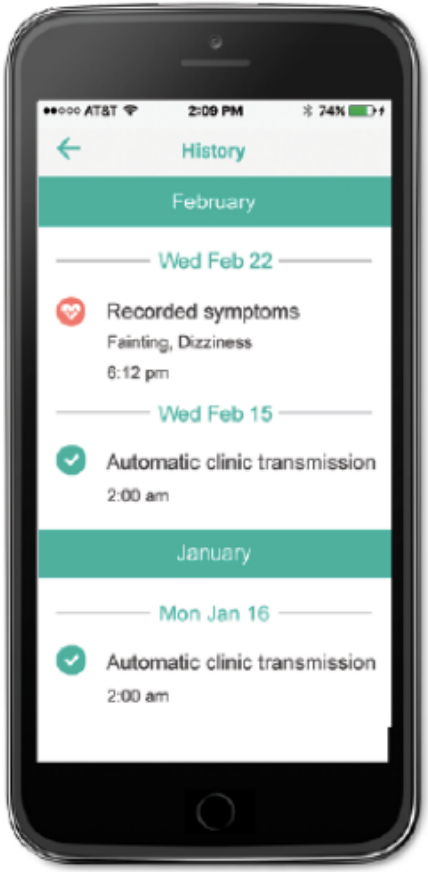
INSTITUT DE CARDIOLOGIE DE MONTRÉAL

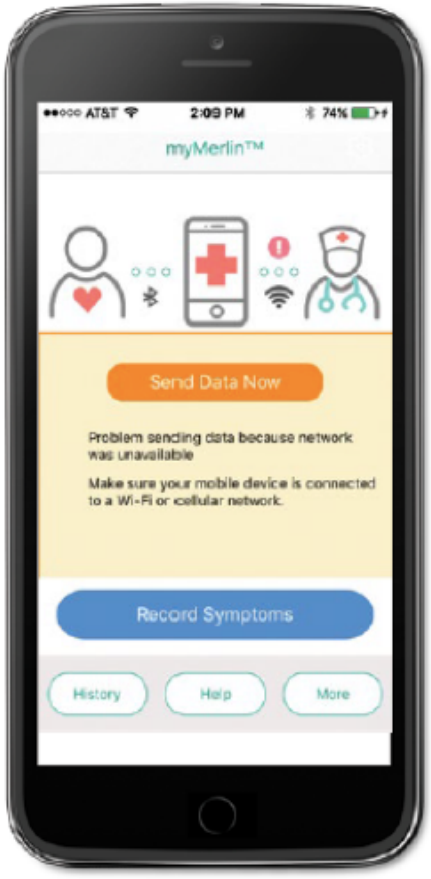
CONFIRM RX


OR
Confirm Rx™ ICM
Patient Smartphone
Transmitter and Activator
(iOS™ software or Android™ software)
Clinician Portal
Merlin.net™ PCN

CONFIRM RX


AT&T 2:09 PM 74%
myMerlin™
3:50
What symptoms are you having?
Fainting
Dizziness
Fluttering
Shortness of breath
Fast heart rate
Other
Done


AT&T 2:09 PM 74%
History
February
Wed Feb 22
Recorded symptoms
Fainting, Dizziness
6:12 pm
Wed Feb 15
Automatic clinic transmission
2:00 am
January
Mon Jan 16
Automatic clinic transmission
2:00 am


AT&T 2:09 PM 74%
myMerlin™
Send Data Now
Problem sending data because network was unavailable
Make sure your mobile device is connected to a Wi-Fi or cellular network.
Record Symptoms
History
Help
More

Longevity	2 years†
Detection Sampling Rate	512 Hz
Patient Trigger	Yes
Symptom Alert	Off
	On (All Symptoms)
	On (with Detection)
Remote Monitoring	myMerlin™ app via Bluetooth® wireless technology
Patient Activator	myMerlin™ app via Bluetooth® wireless technology
Tachycardia Trigger and Alert	Yes
Bradycardia Trigger and Alert	Yes
Pause Trigger and Alert	Yes
Atrial Fibrillation Trigger and Alert	Yes
Programmable AF Episode Duration	30 seconds, 1, 2, 6, 10, 20, 30, 60 minutes
AF Burden Alert	Off, 30 minutes, 1, 3, 6, 9, 12, 24 hours
AF Continuous Episode Alert	Off, 1, 2, 6, 10, 20, 30, 60, 180 minutes
Ventricular Rate during AF Alert	Off
	90 – 150, 175, 200 bpm
	1, 3, 6, 9, 12 hours
Activity Inhibits Auto Detection	Programmable, On or Off
Noise Response Inhibits Auto Detection	Yes

Diagnostics

Episodal Diagnostics	Yes
Total EGM Storage	60 minutes
Symptom EGM Duration	Pre-trigger - 4, 6, 8, 10, 12, 14 minutes
	Post-trigger - 30, 40, 50, 60 seconds
Auto Detected EGM Duration	AF Pre and Post-Trigger - 10, 20, 30, 40, 50, 60 & 120 sec
	Other (Tachy, Brady, Pause) Pre and Post-Trigger – 10, 20, 30, 40, 50 & 60 secs
EGM Sampling Rate	128 Hz
Heart Rate Histogram	Yes
AF Diagnostics	Yes
AF Burden Trend	Yes

	Reveal linq	Biomonitor 2	Confirm Rx
Size in mm Volume Weight	44.8*7.2*4.0 1.2 cc 2.5 g	88.4*15.2*6.2 5 cc 10.1 g	49.0*9.4*3.1 1.4 cc 3 g
RMI compatibility	1.5T and 3T	1.5T and 3T	1.5T
Home monitoring	Medtronic MyCarelink™	Biotronik Home Monitoring	myMerlin™ mobile app
Longevity	3y	4y	2y
Total EGM storage	27 min (automatically) 30 min (pt activated) 4*7.5 min 3*10 min 2* 15 min	60 min 6 triggers (3 episodes per trigger)	60 min

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Merci!