REMOTE MONITORING of patients with cardiac devices can help lead to improved clinical outcomes\(^1\) and economic benefits.\(^2\) Patient utilization and workflow optimization are key to realizing this value.
PATIENT MANAGEMENT

Begins immediately after implant, enabling early clinical intervention and improved outcomes.¹
MANAGING RISK FOR DEVICE PATIENTS

Patients who are at risk benefit from early detection.

Example: Asymptomatic Atrial Fibrillation and Stroke Risk

2.5x

= INCREASED STROKE RISK
for pacemaker patients with device detected asymptomatic atrial tachyarrhythmias (AT/AF) (p = 0.007)³

35%

of pacemaker patients have asymptomatic AT/AF³

AT/AF EPISODES AS SHORT AS 6 MINUTES in duration increase the risk of stroke³

35 DAYS

= MEDIAN TIME to first detection of asymptomatic AT/AF by pacemakers³

The ASSERT study “shows clearly for the first time that silent atrial fibrillation in patients with pacemakers is in fact associated with quite a large increased risk of stroke.”

Dr. Stuart J. Connolly⁴
ENABLING PROACTIVE CARE
Remote monitoring supports early clinical intervention to help reduce patient risk.

79% REDUCTION IN TIME TO A CLINICAL DECISION
Clinicians take 4.6 days to reach a clinical decision with remote monitoring vs. 22 days using in-office follow-up. A arrhythmic events are detected earlier (21-35 days). Arrhythmic events are detected earlier (21-35 days).
A mean 117-day gain in event detection is realized (p = 0.001).  

2.4x GREATER PROBABILITY OF SURVIVAL
Remote monitoring more than doubles a patient's probability of survival versus patients not remotely monitored. A 50% lower risk of all-cause mortality in ICD patients can be achieved. 

BEGIN MONITORING DAY 1
Patients can be monitored immediately after the device is implanted. Same day discharge of patients is clinically feasible and may help reduce hospitalization costs.
PATIENT UTILIZATION

from day 1 is key to realizing the value of remote monitoring

PATIENT TRANSMITTER UTILIZATION

Point of Care Pairing⁹ 91%
Cronin et al.¹⁸ 51%
CONNECT Trial⁴ 55%
**THE CHALLENGE OF POOR PATIENT UTILIZATION**

Important clinical diagnostics can only be sent to a clinician if the patient’s transmitter is active.

**Patient Transmitter Utilization: Comparison of Published Benchmarks***

<table>
<thead>
<tr>
<th>%</th>
<th>0</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONNECT Trial</strong></td>
<td>55%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>100% Medtronic™ ICDs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cronin et al.</strong></td>
<td>51%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10%</td>
<td>56.4% Medtronic™ devices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

45% of automatic clinical alerts are not successfully transmitted because the home monitor is not properly set up by the patient.5

Poor utilization creates workflow inefficiencies.10

*Refer to the individual studies for definitions of utilization in each study.*
In-office setup of the wireless transmitter is associated with significantly superior patient utilization, which is the key to remotely managing patients with implantable cardiac devices for improved outcomes.

---

**Patient Transmitter Utilization: Comparison of Published Benchmarks**

<table>
<thead>
<tr>
<th>Study/Source</th>
<th>Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONNECT Trial</td>
<td>55%</td>
</tr>
<tr>
<td>Cronin et al.</td>
<td>51%</td>
</tr>
<tr>
<td>Point of Care Pairing</td>
<td>91%</td>
</tr>
</tbody>
</table>

---

“...in-office setup is associated with significantly superior patient utilization, which is the key to remotely managing patients with implantable cardiac devices for improved outcomes.”

*Xiushui Ren, MD*¹¹

---

*Refer to the individual studies for definitions of utilization in each study.*
**IMPROVING UTILIZATION AND EXPANDING PATIENT ACCESS**

Communication options take the burden off the patient.

“The Microcomputer In Your Chest Needs A Landline”

*(Wall Street Journal Health Blog, 6/26/2012)*

Internet and cellular communication is increasing while landline usage is declining.

**Broadband Internet**

- 57% of people age 65+ use the Internet\(^1\)\(^2\)

**Cellular**

- 40% of adults only have wireless telephone service\(^1\)\(^3\)
ACTIVATING A REMOTE TRANSMITTER

can more than double a patient’s probability of survival.¹,⁸

REDUCED RISK, REDUCED MORTALITY¹,⁸
50% lower risk of all-cause mortality
2.4x greater probability of survival
**REDUCING MORTALITY RISK**

Patients who utilize their transmitter for remote monitoring experience better outcomes.

---

**ICD/CRT-D PATIENTS**

Retrospective analysis reveals a potential **50% LOWER RISK** of all-cause mortality in ICD patients.\(^1\)\(^4\)

**PACEMAKER PATIENTS**

Retrospective analysis reveals a potential **27% REDUCTION** in all-cause mortality over 3 years.\(^5\)

---

**INCREASED PROBABILITY OF SURVIVAL**

observed in patients with highest adherence to remote monitoring.\(^7\)

---

**SURVIVAL, ALL DEVICE TYPES**

<table>
<thead>
<tr>
<th>Proportion Surviving</th>
<th>Years from Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients:</th>
<th>Pacemaker</th>
<th>ICD</th>
<th>CRT-D</th>
<th>CRT-P</th>
</tr>
</thead>
</table>

---

**Patients: | Pacemaker | ICD | CRT-D | CRT-P |
|----------|-----------|-----|-------|-------|

**2.4x**

greater probability of survival for patients who utilize remote monitoring vs. those who do not

---

**ICD/CRT-D PATIENTS**

Retrospective analysis reveals a potential **50% LOWER RISK** of all-cause mortality in ICD patients.\(^1\)\(^4\)

**PACEMAKER PATIENTS**

Retrospective analysis reveals a potential **27% REDUCTION** in all-cause mortality over 3 years.\(^5\)

---

**ICD/CRT-D PATIENTS**

**PACEMAKER PATIENTS**

**Notes:**

1. Reference 1
2. Reference 2
3. Reference 3
4. Reference 4
5. Reference 5
6. Reference 6
7. Reference 7
8. Reference 8
9. Reference 9
10. Reference 10
11. Reference 11
12. Reference 12
13. Reference 13
14. Reference 14
REDUCING HOSPITAL ADMISSIONS

Remote monitoring improves clinical outcomes while reducing health care costs.

- **36%** REDUCTION in cardiac or device-related emergency department or hospital visits

- **66%** REDUCTION in hospitalizations for AF or stroke

- **$1,793** STAY SAVINGS due to 18% reduction in mean length of hospital stay

- **18%** REDUCTION in mean length of hospital stay (Estimated savings $1,793/stay)
DEVICE-DRIVEN DIAGNOSTICS
Alert notifications support early clinical intervention.

Alerts
- Manage important device-triggered alerts between follow-ups
- Monitor patient disease status and device performance daily
- Receive immediate notifications for urgent alerts
- Customizable by patient

Early Identification of:
- Atrial Fibrillation
- Ventricular Tachycardia
- Loss of CRT Therapy
REIMBURSEMENT EFFICIENCY

is realized with active patients providing a recurring revenue stream.

FREQUENCY

Pacemakers: 91 days
ICD/CRT-Ds: 91 days
Physiologic Monitoring: 31 days
## Reimbursement Frequency

Regular reimbursement is available for arrhythmia and heart failure diagnostics.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker</td>
<td>91 Days</td>
<td>$71.00 Professional + $33.00 Technical</td>
<td>$44.00 Professional + $20.00 Technical</td>
<td>+ $27.00</td>
</tr>
<tr>
<td>ICD/CRT-D</td>
<td>91 Days</td>
<td>$108.00 Professional + $33.00 Technical</td>
<td>$76.00 Professional + $25.00 Technical</td>
<td>+ $32.00</td>
</tr>
<tr>
<td>Physiologic Monitoring</td>
<td>31 Days</td>
<td>$55.00 Professional + $26.00 Technical*</td>
<td>$36.00 CPT™ code 93290 Global Code</td>
<td>+ $19.00</td>
</tr>
</tbody>
</table>

Contact a Reimbursement Specialist: 855-569-6430

Source: CY 2015 Physician Fee Schedule final rule
Assumption: Using remote monitoring for routine follow-ups of asymptomatic patients (1 check every 91 days + 1 check every 31 days for Physiologic Monitoring.)

*Assumes technical component will be reimbursed at same rate as pacemaker and ICD/CRT-D technical service. The technical component is carrier priced based on the local Medicare Administrative Contractor.
SCHEDULING OF REMOTE CHECKS

Automatic scheduling aligns remote checks with billing frequency.

- Patients who are not active miss their scheduled checks.
- Manual schedules are difficult to maintain consistently.
- Automatic scheduling of patients with wireless devices allows the clinic to schedule and bill all appropriate device checks.
REDUCTION OF COST to the health care system is realized for patients who are active with remote monitoring.

REDUCTION IN TOTAL SPENDING OVER THREE YEARS

Pacemaker Patients: 9% ($4,356 per patient)
ICD/CRT-D Patients: 17% ($10,640 per patient)
**FOCUSBING ON EXPENSIVE DISEASE STATES**

Remote monitoring is a critical tool in population health management.

**Atrial Fibrillation**

35% increase in spending over three years on pacemaker patients with AF\(^1\)

Pacemaker Patient Comparison: AF vs. Non-AF by Medicare Cost Category Over Three Years

![Graph showing cost comparison between AF and Non-AF patients across various categories.](image)

- **Total Spend**
  - AF (n = 5,733) $46,958
  - Non-AF (n = 14,212) $26,609

- **Cost increase per patient**
  - Inpatient: +35%
  - Hospital Outpatient: +48%
  - Physician: +19%
  - Skilled Nursing: +52%
  - Home Health: +24%
  - Hospice: +11%
  - Durable Medical Equipment: +11%

**Heart Failure**

$34.4 B estimated annual cost (direct and indirect) for HF in the US\(^2\)

Largest Contributors to Medicare Spending on Potentially Preventable Readmissions ($ Millions)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cost (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Failure</td>
<td>$518.2</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>$468.3</td>
</tr>
<tr>
<td>PTCA</td>
<td>$379.2</td>
</tr>
<tr>
<td>COPD</td>
<td>$317.5</td>
</tr>
<tr>
<td>Other Vascular</td>
<td>$256.8</td>
</tr>
<tr>
<td>CABG</td>
<td>$206.7</td>
</tr>
<tr>
<td>AMI</td>
<td>$163.9</td>
</tr>
</tbody>
</table>
REDUCING TOTAL COST

Patients with remote monitoring cost less to manage across the health care system.

Pacemaker Patients
9% reduction in total spending over three years\(^2\)
= $4,356 per patient

ICD/CRT-D Patients
17% reduction in total spending over three years\(^2\)
= $10,640 per patient

With AF
\(p = 0.0262\)
No AF
\(p = 0.0121\)

n = 3219  n = 8404  n = 2976  n = 2828

Three-Year Total Medicare Spending

Without Monitoring
With Monitoring

\(\text{No Remote Monitoring} \quad \text{Remote Monitoring}\)

n = 3219  n = 516  n = 8404  n = 1267

\(\text{No Remote Monitoring} \quad \text{Remote Monitoring}\)

n = 2976  n = 2828
**BUDGETARY IMPACT MODEL**

A customized analysis of cost saving and reimbursement for remote monitoring across a patient population.

---

### References

- **IMPLANT ››**
- **PATIENT UTILIZATION ››**
- **PATIENT OUTCOMES ››**
- **REIMBURSEMENT ››**
- **COST AVOIDANCE ››**
- **WORKFLOW EFFICIENCY ››**

---

### Annual Patient Volume

<table>
<thead>
<tr>
<th>ICD/CRT-D</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>50%</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$8,361,400</td>
</tr>
</tbody>
</table>

---

### Pacemaker

<table>
<thead>
<tr>
<th>Current Scenario</th>
<th>Potential Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Enrollment</td>
<td>60%</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$497,146</td>
</tr>
</tbody>
</table>

---

### ICD/CRT-D

<table>
<thead>
<tr>
<th>Current Scenario</th>
<th>Potential Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Enrollment</td>
<td>40%</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$497,146</td>
</tr>
</tbody>
</table>

---

### Patient Compliance

- 91% increase in patient compliance
- Prospective follow-up of patients within a closed system has demonstrated an increase in patient compliance of 91%.

---

### Budgetary Impact Model Results: Remote Patient Management with Merlin.net™ Patient Care Network

**Introduction**

The prevalence of patients treated with cardiac implantable electronic devices such as pacemakers and implantable cardioverter-defibrillators (ICDs) has increased in recent years, as has the complexity of their use in clinical settings of care. Patients implanted with these devices, often referred to as "device patients," require ongoing monitoring and management for both clinical and technical platforms, such as anticoagulation or device interrogation. As the nature of patients with cardiac disease has grown, remote monitoring has emerged as a proven, with few, and increasingly essential care delivery model.*

**Model Highlights**

The model highlights the potential economic impact of successfully patient enrollment into and compliance with remote monitoring programs. Proactive follow-up of patients within a closed system has demonstrated an increase in patient compliance of 91%, when compared to traditional, in-office monitoring practices.

---

### Competitive Comparison

- **St. Jude Medical**
  - U.S. Division
  - Building Two, Suite 100
  - 6300 Bee Cave Road
  - Austin, Texas 78746
  - Tel: 512-350-3100
  - Fax: 512-350-3162

---

Available from your St. Jude Medical Representative
SAME-DAY DISCHARGE

Outpatient procedures are clinically feasible and can result in cost savings versus in-patient procedures.

<table>
<thead>
<tr>
<th></th>
<th>Choudhuri et al.\textsuperscript{14}</th>
<th>Darda et al.\textsuperscript{18}</th>
<th>Elmouchi et al.\textsuperscript{19}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>71</td>
<td>415</td>
<td>800+</td>
</tr>
<tr>
<td>Devices</td>
<td>ICDs</td>
<td>ICDs</td>
<td>HV/LV</td>
</tr>
<tr>
<td>Savings</td>
<td>$150,000</td>
<td>$5,590/patient</td>
<td>$1,760,000/18 mo</td>
</tr>
</tbody>
</table>

\textsuperscript{18} INSTITUTIONAL SAVINGS over 18 months\textsuperscript{13} due to same day discharge
A STREAMLINED CLINIC WORKFLOW

helps with management of remote monitoring data.
POOR PATIENT UTILIZATION COMPLICAATES CLINIC WORKFLOW

Missed scheduled checks and manual processes can burden clinic staff.

- Patients routinely miss scheduled checks when it requires their involvement.
- Clinic staff spend time calling patients who are not active.\(^\text{10}\)
- Clinic staff spend time manually entering, printing and scanning data.
- Device clinics control the schedule for wireless devices.
- Active patients help staff focus on patient care.
- Data automation can reduce redundant data entry and data entry errors.
INTEGRATING DATA IN THE ELECTRONIC HEALTH RECORD (EHR)

Centralize patient records to inform clinical care decisions.

**Access Complete Patient Records**

View medications, lab results and device data in a single place.

**Optimize Workflow**

Case Study: Colorado Health Medical Group, Cardiology, Fort Collins, Colorado

Total workflow minutes per remote check\(^20\)

<table>
<thead>
<tr>
<th>Previous Workflow</th>
<th>Improved Workflow with EHR Integration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manually Populate EHR Template</strong></td>
<td><strong>Process Transmission</strong></td>
</tr>
<tr>
<td><strong>Manually Update Template</strong></td>
<td><strong>Process Transmission</strong></td>
</tr>
<tr>
<td>Minutes - 0 2 4 6 8 10 12 14 16 18 20</td>
<td>Minutes - 0 2 4 6 8 10 12 14 16 18 20</td>
</tr>
<tr>
<td><strong>Process Transmission</strong></td>
<td><strong>Process Transmission</strong></td>
</tr>
</tbody>
</table>

Reimbursement Per Workflow Hour\(^20\)

- $254
- $1,216
EFFICIENT WORKFLOW

Streamline and accelerate workflow from initial procedure to remote device transmission and final reimbursement.
## COMPETITIVE COMPARISON

<table>
<thead>
<tr>
<th>SUPPORTED DEVICES</th>
<th>ST. JUDE MEDICAL</th>
<th>MEDTRONIC</th>
<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF ICDs/CRT-Ds</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>RF Pacemakers</td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TRANSMITTER CONNECTIVITY</th>
<th>ST. JUDE MEDICAL</th>
<th>MEDTRONIC</th>
<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
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<tbody>
<tr>
<td>Landline</td>
<td>✔</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Cellular</td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>Broadband Internet</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TRANSMITTER ACTIVATION</th>
<th>ST. JUDE MEDICAL</th>
<th>MEDTRONIC</th>
<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point of Care Pairing</td>
<td>✔</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Published Utilization Metric</td>
<td>91%</td>
<td>55%</td>
<td>76%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TRANSMISSION DIAGNOSTICS</th>
<th>ST. JUDE MEDICAL</th>
<th>MEDTRONIC</th>
<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD/CRT-D: stored EGMs</td>
<td>✔</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Pacemaker: stored EGMs</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
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<table>
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<tr>
<th>SCHEDULING</th>
<th>ST. JUDE MEDICAL</th>
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<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic Scheduling</td>
<td>✔</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Manual Scheduling</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>91- or 182-day Options to Align with Billing</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Same-Day Discharge w/Automatic Confirmation by Scheduled Transmission</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CLINIC MANAGEMENT</th>
<th>ST. JUDE MEDICAL</th>
<th>MEDTRONIC</th>
<th>BOSTON SCIENTIFIC</th>
<th>BIOTRONIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct EHR Interface (discrete data, PDFs, EGMs)</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Data Management Systems</td>
<td>ScottCare OneView™ System Partnership</td>
<td>Paceart™ System</td>
<td>ScottCare OneView™ System Partnership</td>
<td>ScottCare OneView™ System Partnership</td>
</tr>
<tr>
<td>Automatic Patient Calls</td>
<td>✔</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

### NOTES
- Still evaluating how to launch with other devices beyond LINQ
- New transmitter is cellular only
- CareLink Monitor Upgrade Program, moves existing analog transmitters to cellular, internet-based and mobile app-based technologies. Begins November 2015.
- ICDs and pacemakers on separate monitoring platforms (Latitude and Latitude NXT)
- Transmitter pairing via website (NXT only), waiting period before transmission
- No RF at implant
- Scheduling note: users select from all transmissions to determine when to bill
- Remote transmission dates correspond to programmer system date (must be set in office)
References

1. Mittal, S. (2014). Remote Monitoring of ICD Patients is Associated with Reduced Mortality Irrespective of Device Type. HRS 2014. San Francisco, California. May 7-10, 2014. AB18-01. This was a retrospective data review and has limitations.


16. Retrospective claims analysis of Medicare 5% sample Limited Data Set Standard Analytical Files claims and enrollment data. The analysis identified all pacemaker implants and revisions in the sample from the 2006 and 2007 calendar years (totaling 19,954 cases across all manufacturers). Cases were identified in which patients were alive in the quarter following the implant. Costs and outcomes were calculated for the three years following implant, and “pacemaker-only” cases were segregated from “pacemaker/AF diagnosis” cases. The analysis included AF diagnoses identified at any point in the two quarters prior to implant and up to six quarters post-implantation.


