**Study Overview**

The purpose of this clinical investigation was to demonstrate the safety and navigation performance of Amigo. 206 patients were enrolled at 13 centers and data was collected and evaluated on safety, efficacy, and the learning curve of Amigo.

**Navigation Performance**

Using the remote controller, the catheter was advanced to 8 pre-specified locations in a specific sequence.

Time to each location, location accuracy and quality of contact was confirmed by imaging with specific criteria for electrograms and pacing thresholds.

A point was considered a success if all required data was collected.

A total of 1448 locations were mapped.

**Navigation Success Rate**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>96%</td>
</tr>
<tr>
<td>Efficacy adjusted for missing source data</td>
<td>97%</td>
</tr>
<tr>
<td>Efficacy using floroscopic confirmation only</td>
<td>99%</td>
</tr>
<tr>
<td>Responder Success (6/8 locations successful)</td>
<td>98%</td>
</tr>
</tbody>
</table>

**Safety Results**

Safety was determined by:

- No Major Complications
- No unanticipated Adverse Events
- No Perforations

**Physician Evaluation**

After each procedure, the physician filled out a questionnaire related to ease of use of Amigo and catheter control with Amigo.

- In 92% of first cases, investigators found Amigo easy to operate
- In 98% of subsequent cases, investigators found Amigo was easy to operate.

**Learning Curve**

The average manipulation time required to reach a location was 45 seconds.

The first procedure had the longest average manipulation time but a statistically significant decrease occurred by the 3rd use.

Physician learning curve was only associated with proficiency in using Amigo and not with complications.

**Navigation Times**

![Graph showing average manipulation time per location](image)

All data based on Amigo IDE Clinical Trial (NCT01139814)
Amigo Remote Catheter System

Amigo is a new generation of robotic catheter systems. It utilizes a simple design and a familiar controller. It was developed with three goals in mind:

• Simple to use
• Easy to learn
• Cost effective

Safe, Consistent Performance

• 99% of target locations are reached with Amigo¹
• 0% major complication rate¹

Effortless Learning

Requiring less than one hour of practice, and no animal labs, Amigo is designed to be easy to learn. There are statistically significant decreases in navigation times after only 3 patients.¹

• In 92% of first cases physicians found Amigo easy to use¹
• Similar to a catheter handle, the controller is intuitive and familiar

Seamless Integration

Amigo was designed to be cost effective. To achieve this goal, engineers designed Amigo to fit into an existing EP Laboratory with no additional costs.

• Compatible with existing monitors and workstations
• No room rebuild
• No proprietary catheters, introducers, or sheaths, maintaining procedure costs

¹ Amigo IDE Clinical Trial (NCT01139814)

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Amigo Technical Specs

<table>
<thead>
<tr>
<th>Dimension (H x W x D)</th>
<th>40 x 54 x 44 inches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (approximate)</td>
<td>70 lbs</td>
</tr>
<tr>
<td>Performance</td>
<td></td>
</tr>
<tr>
<td>Linear translation</td>
<td>&lt; 12 mm/sec ± 2 mm/sec</td>
</tr>
<tr>
<td>Linear resolution</td>
<td>&lt; 1.6 mm</td>
</tr>
<tr>
<td>Rotation resolution</td>
<td>&lt; 1.1 degrees</td>
</tr>
<tr>
<td>Rotation maximum rate</td>
<td>&lt; 0.42 revs/sec</td>
</tr>
<tr>
<td>Articulation resolution</td>
<td>&lt; 1.0% full scale</td>
</tr>
<tr>
<td>Articulation maximum rate</td>
<td>0.48 revs/sec</td>
</tr>
<tr>
<td>Facility Power Requirements</td>
<td>120 VAC, 60 Hz, 15 amp, 1Ø</td>
</tr>
<tr>
<td></td>
<td>230 VAC, 50 Hz, 15 amp, 1Ø</td>
</tr>
</tbody>
</table>

Navigation Times

![Average Manipulation Time per Location](chart)

Mean Manipulation Time

Number of Cases

1  2  3

Mean Manipulation Time

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Controller

**Intuitive Control**

- Natural and easy to learn
- Built in safety features
- Simple catheter control up to 100 feet away

**Simple, Familiar Design**

Rotation knob allows for continuous 360° rotation of the catheter in either direction.

The Motion Light indicates when the catheter has reached the maximum movement in a particular direction.

Deflection knob allows for bidirectional control of the catheter tip.

Insert button advances the catheter into the heart.

Withdraw button pulls the catheter back to be withdrawn.

Ready Light indicates when the system's infrared beam has been activated.

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1 Amigo IDE Clinical Trial (NCT01139814)
**Disposable Kit**

The disposable kit is designed to create a sterile interface between Amigo, the catheter and the physician. The nosecone attaches Amigo to the introducer and the catheter resides within the track, adding stability to the catheter.

The drapes cover the sides and top of Amigo to provide a complete sterile interface.

This kit is comprised of a docking station and a spreader. This item is specific to the type of catheter used and can be ordered in a Boston Scientific Blazer orientation or a Biosense - Webster EZ Steer™ orientation. The docking station provides an interface for the catheter to attach to Amigo and the spreader guides the catheter into the track.