

MEDIGUIDE™ TECHNOLOGY: NAVIGATING AWAY FROM LIVE X-RAY

Clinical Compendium

MediGuide™ Technology is the first and only solution to enable navigation of devices on pre-recorded X-ray images, allowing the physician to reduce fluoroscopy time and radiation dose without increasing procedure time. The ability to use pre-recorded X-ray images, instead of live X-ray, is consistent with the radiation principle, As Low As Reasonably Achievable (ALARA). MediGuide Technology addresses both the principle to reduce fluoroscopy time, and the need to improve visualization and navigation in cardiac intervention procedures.

This compendium summarizes the latest clinical research and evidence generated using MediGuide Technology to facilitate complex electrophysiology¹⁻¹⁸ and cardiac resynchronization therapy (CRT)¹⁹⁻²⁴ procedures. Clinical evidence from multiple peer-reviewed publications has shown that MediGuide Technology is associated with statistically significant reductions in fluoroscopy time and radiation dose, with no significant increases in total procedure time, when used in a variety of electrophysiology procedures,^{1-3,5,7,9-14} and during CRT device implant procedures.^{19,20,22,24} Procedural success and complication rates were similar in the MediGuide groups and conventional groups included in these studies.^{1-14,19-21}

ENHANCED FEATURES FACILITATE ELECTROPHYSIOLOGY PROCEDURES WITH FLUOROSCOPY AND RADIATION DOSE REDUCTIONS

MediGuide™ Technology integrates 3-D non-fluoroscopic catheter navigation into the environment of pre-recorded conventional 2-D fluoroscopy. The system allows for precise, real-time catheter tracking within the cardiac chamber on pre-recorded X-ray images. The studies summarized in the table below and on the following pages provide clinical evidence supporting the use of MediGuide Technology to facilitate electrophysiology (EP) procedures with reduced fluoroscopy and radiation dose compared with conventional electroanatomical mapping and catheter visualization systems in patients with a variety of diagnoses.

Summary of Peer-Reviewed Published Clinical Data with MediGuide™ Technology in Electrophysiology Procedures

Study, Year	Study Type	Procedure Type(s)	Fluoroscopy Time/ [Total Procedure Time, if reported] (no. of patients per group)			Radiation Dose			Acute Procedural Success	Complications
			MediGuide	Conventional	P-value	MediGuide	Conventional	P-value		
Mansour, 2015 ¹	Prospective two-center observational study with matched cohort control data	Transseptal puncture during AF ablation (n = 32)	0.48 min* (n = 16)	5.9 min* (n = 16)	< 0.0001	13.8 mGy*	390 mGy*	< 0.001	100%	No major complications during procedures in either group
Malliet, 2015 ²	Prospective, single-center, consecutive two-group cohort study	AF ablation (n = 44)	12.5 min [169 min] (n = 22)	21.5 min [160 min] (n = 22)	< 0.0001 [0.9954]	1107 µGy·m ²	2835 µGy·m ²	0.0001	100%	No complications noted in either group or procedure type
		AFL ablation (n = 90)	0.8 min [89.5 min] (n = 48)	9.9 min [82.5 min] (n = 42)	< 0.0001 [0.4286]	161 µGy·m ²	1651 µGy·m ²	< 0.0001		
Schoene, 2015 ³	Prospective, randomized, single-institution study	AFL ablation (n = 40)	0.3 min [49.5 min] (n = 20)	5.7 min [33.5 min] (n = 20)	< 0.001 [0.053]	17.4 cGy·cm ²	418 cGy·cm ²	< 0.001	100%	No adverse events reported
Sommer, 2014 ⁴	Analysis of prospective, consecutive, single-center registry data	AF ablation (n = 375)	2.8 min [145 min] (n = 375)	NA	NA	789 cGy·cm ²	NA	NA	99%	Complications in 10 (2.7%) of patients
Vallakati, 2013 ⁵	Analysis of prospective, non-randomized, two-center observational registry data	RF ablation: AFL (n = 66), AVNRT (10), WPW (8); diagnostic (no ablation, n = 6) (n = 90)	8.3 min* [104 min*] (n = 45)	21.2 min* [142 min*] (n = 45)	< 0.001 [0.03]	685 mGy*	1782 mGy*	< 0.001	100%	No major procedural complications or acute adverse effects
Rolf, 2013 ⁶	Prospective, single-institution observational study	AF ablation (n = 80)	4.4 min [167 min] (n = 80)	NA	NA	2115 cGy·cm ²	NA	NA	98%	Three (4%) minor complications
Sommer, 2013 ⁷	Analysis of prospective, consecutive, two-center registry data	SVT ablation: AFL (n = 1003), AVNRT (468), WPW (318), EAT (76)	0.5 min [70 min] (n = 24)	10.2 min [60 min] (n = 1865)	< 0.001 [n.s.]	187 cGy·cm ²	996 cGy·cm ²	< 0.05	100% (MediGuide) 98% (Conv.)	No adverse events in 3 days post-procedure
Sommer, 2013 ⁸	Prospective study of consecutive patients	AFL ablation (n = 10)	2.5 min* [55.2 min*] (n = 10)	NA	NA	1355 cGy·cm ²	NA	NA	100%	No adverse events during procedures
Rolf, 2012 ⁹	Prospective, single-institution non-randomized study with retrospectively matched control	AF ablation (n = 98)	16 min [174 min*] (n = 49)	31 min [157 min*] (n = 49)	< 0.001 [0.06]	7363 cGy·cm ^{2*}	14,453 cGy·cm ^{2*}	< 0.001	100%	Minor complications post-ablation in 2 (4%) patients in each group

Time and dose values are medians except as noted (*mean value); AF = atrial fibrillation, AFL = atrial flutter, AVNRT = atrioventricular nodal reentrant tachycardia, WPW = Wolf-Parkinson-White syndrome, EAT = ectopic atrial tachycardia; NA = not applicable, n.s. = not significant.

Feasibility of Transseptal Puncture Using a Nonfluoroscopic Catheter Tracking System

Mansour, et al. *Pacing and Clinical Electrophysiol*, 2015¹

- This prospective observational study assessed the feasibility of performing transseptal (TS) puncture with MediGuide™ Technology MediGuide assistance in 16 patients undergoing RF ablation for atrial fibrillation.
 - A matched cohort of 16 patients undergoing TS access using conventional fluoroscopy was used for comparison (control group).
- All patients underwent successful TS puncture.
- Fluoroscopy time for double TS puncture using the MediGuide System was significantly lower than the control group (0.48 ± 0.17 minutes vs. 5.9 ± 0.65 minutes; p < 0.0001).
- No major complications occurred during the procedures in either group.

Key takeaway:

- MediGuide Technology can be used to successfully assist in performing TS puncture, resulting in significant reduction in radiation exposure compared to TS puncture using conventional fluoroscopy.

Impact of a Novel Catheter Tracking System on Radiation Exposure during the Procedural Phases of Atrial Fibrillation and Flutter Ablation

Malliet, et al. *Pacing and Clinical Electrophysiol*, 2015²

- This study prospectively enrolled consecutive patients referred for ablation of atrial fibrillation (AF, n = 44) or atrial flutter (AFL, n = 90) with or without the novel non-fluoroscopic sensor-guided catheter electromagnetic MediGuide System (MG).
- The use of the MediGuide System was associated with significant reductions in radiation exposure by 60% during AF ablation and 90% during AFL ablation procedures when compared to conventional fluoroscopy guided procedures (see table for median [interquartile range] values).

AF Ablation Procedures	MediGuide (n = 22)	Conventional (n = 22)	P-value
Procedure duration (min)	168.5	159.5	p = 0.9954
Total fluoroscopy time (min)	12.5 [7.6, 17.4]	21.5 [15.3, 23.0]	p < 0.0001
Radiation dose (μGy·m ²)	1107 [9.6, 2033]	2835 [1688, 3855]	P = 0.0001

AFL Ablation Procedures	MediGuide (n = 48)	Conventional (n = 42)	P-value
Procedure duration (min)	89.5	82.5	p = 0.4286
Total fluoroscopy time (min)	0.8 [0.4, 2.5]	9.9 [5.1, 22.5]	p < 0.0001
Radiation dose (μGy·m ²)	161 [65, 537]	1651 [796, 4569]	p < 0.0001

- In the MediGuide group, 22 of 48 AFL procedures were completed with no additional fluoroscopy after baseline cine loops were recorded.
- No differences in total procedural times were seen.
- No complications were noted.

Key takeaways:

- The use of the MediGuide™ System was associated with a significant reduction in radiation exposure during AF and AFL ablation versus conventional fluoroscopy guidance.
- The MediGuide System is a safe and efficient tool to decrease radiation exposure during electrophysiological ablation procedures.

Ablation of Typical Atrial Flutter Using a Non-fluoroscopic Catheter Tracking System vs. Conventional Fluoroscopy—Results from a Prospective Randomized Study

Schoene, et al. *Europace*, 2015³

- This first prospective randomized study from Leipzig compared the effects of using MediGuide Technology non-fluoroscopic catheter tracking (n = 20) versus conventional fluoroscopy (n = 20) on procedural parameters in patients undergoing radiofrequency ablation of typical atrial flutter.
- Bidirectional isthmus block was achieved in all patients.
- Fluoroscopy time and radiation dose were significantly reduced in the MediGuide System group when compared with the conventional group (see table for median [interquartile range] values).

AF Ablation Procedures	MediGuide (n = 20)	Conventional (n = 20)	P-value
Procedure duration (min)	49.5 [37, 65]	33.5 [26.3, 55.5]	p = 0.053
Total fluoroscopy time (min)	0.3 [0.2, 0.48]	5.7 [4.2, 11.5]	p < 0.001
Radiation dose (cGy·m ²)	17.4 [11, 206.6]	418.4 [277, 812.2]	p < 0.001

- There was no significant difference in total procedure duration, and no adverse events were recorded.
- Freedom from atrial flutter at six months was similar between the two groups: 19/20 (95%) in the MediGuide System and 18/20 (90%) in the conventional group.

Key takeaways:

- The use of the MediGuide System significantly reduced both radiation dose and fluoroscopy time in this randomized study.
- These findings support the incorporation of non-fluoroscopic catheter tracking in routine clinical use.

Non-Fluoroscopic Catheter Visualization in AF Ablation: Experience from 375 Consecutive Procedures

Sommer, et al. *Circulation: Arrhythmia and Electrophysiology*, 2014⁴

- This prospective AF ablation registry reports on the use of the MediGuide™ System during pulmonary vein isolation (PVI) procedures conducted by six different operators (n = 375).
- Median values for procedure time, fluoroscopy time and radiation dose were 145 ± 45 min, 2.8 min [1.5; 4.4] and 789 cGy·cm², respectively.
- A comparison between the first 50 cases (group I) and last 50 cases (group II) showed statistically significant decreases in all three categories (see table).

PVI Procedures	Group I (first 50 cases)	Group II (last 50 cases)	P-value
Procedure duration (min)	169 ± 49	128 ± 39	p < 0.001
Total fluoroscopy time (min)	6.0 [4.1, 10.3]	1.1 [0.7, 1.5]	p < 0.001
Radiation dose (cGy·m ²)	2363 [1413, 3475]	490 [230, 654]	p < 0.001

- The overall complication rate was reported as 2.7%, which the authors state is comparable to previously published data.⁹

Key takeaways:

- This registry is the largest study to date that reports on the safety of the MediGuide System in PVI procedures.
- These data also suggest that significant decreases in procedure time and the fluoroscopy time could be associated with the operator's increased familiarity with the system over time.

Impact of Nonfluoroscopic MediGuide™ Tracking System on Radiation Exposure in Radiofrequency Ablation Procedures (LESS-RADS Registry): An Initial Experience

Vallakati, et al. *Journal of Interventional Cardiac Electrophysiology*, 2013⁵

- This prospective, observational study evaluated the impact of MediGuide™ Technology on procedural characteristics and fluoroscopic exposure for EP procedures as compared to conventional mapping technologies (n = 90).
- Use of the MediGuide Technology resulted in a significant 61% reduction in cumulative duration of fluoroscopy when compared to the conventional group (see table for mean and p-values).
- With both experienced and less experienced primary operators in the study, there was still a significant difference in fluoroscopy time between groups using MediGuide Technology compared to conventional technology (p < 0.001).

RF Ablation Procedures	MediGuide (n = 45)	Conventional (n = 45)	P-value
Procedure time (min)	103.8 ± 25.3	142 ± 55.8	p = 0.03
Fluoroscopy time (min)	8.25 ± 4.9	21.2 ± 14.8	p < 0.001
Fluoroscopy density (μGy·m ²)	7079 ± 7072	18857 ± 33647	p < 0.001
Fluoroscopy quantity (mGy)	685 ± 751	1782 ± 5153	p < 0.001

- Procedural duration was also significantly reduced by 27% in the MediGuide Technology group compared to the conventional group.
- The use of MediGuide Technology also resulted in a 62% reduction in both fluoroscopy density and fluoroscopy quantity.

Key takeaway:

- Irrespective of operator experience, the incorporation of MediGuide Technology significantly reduces the duration of live X-ray and procedure times in common catheter ablation procedures.

Catheter Ablation of Atrial Fibrillation Supported by Novel Nonfluoroscopic 4D Navigation Technology

Rolf, et al. *Heart Rhythm*, 2013⁶

- This single-institution, observational study reported on the initial clinical use of MediGuide Enabled™ diagnostic and ablation catheters in atrial fibrillation (AF) ablation procedures (n = 80).
- MediGuide Technology was used in addition to the EnSite™ NavX™ technology mapping system; patients underwent circumferential pulmonary vein isolation and voltage mapping with and without substrate modification.
- Mean procedure duration for all patients was 167 ± 47 minutes.
- Median total fluoroscopy time was 4.4 minutes (2.9-7.1 minutes); median fluoroscopy dose was 2115 cGy·cm² (1201-3098 cGy·cm²).
 - Fluoroscopy was primarily used for the acquisition of background loops, transseptal puncture, the occasional verification of transseptal sheath position, and manipulation of the circular mapping catheter.
- The authors noted that with the use of sensor-equipped ablation catheters, the majority of AF ablations may be completed with up to 80% to 90% reduced radiation exposure compared to historical control data from the same institution.⁹

Key takeaway:

- MediGuide Technology integrates easily into the workflow of conventional AF ablation procedures and provides high-quality non-fluoroscopic 4D catheter tracking.

MediGuide™ in Supraventricular Tachycardia: Initial Experience from a Multicentre Registry

Sommer, et al. *Europace*, 2013⁷

- The prospective registry aimed to demonstrate the safety and feasibility of ablation procedures using non-fluoroscopic catheter visualization (n = 24) compared to conventional fluoroscopy (n = 1865).
- Procedural data of consecutive patients scheduled for supraventricular tachycardia (SVT) ablation treated using MediGuide™ Technology were analyzed and compared to consecutive patients who were ablated using conventional technology.
- Ablation success was defined as proof of bidirectional block in atrial flutter, absence of pre-excitation in Wolff-Parkinson-White syndrome (WPW), retrograde conduction block in atrioventricular nodal reentry tachycardia (AVNRT), and as non-inducibility of clinical tachycardia in AVNRT or ectopic atrial tachycardia (EAT).
- Mean radiation dose and median fluoroscopy time for the entire procedure were significantly lower in the MediGuide Technology group versus the conventional group, while mean procedure time was comparable (see table).

SVT Ablation Procedures	MediGuide (n = 24)	Conventional (n = 1865)	P-value
Procedure duration (min)	70 ± 25.5	60 ± 36	p = n.s.
Total fluoroscopy time (min)	0.5 ± 1.4	10.2 ± 9.6	p < 0.001
Radiation dose (cGy·cm ²)	187 ± 554	996 ± 2593	p < 0.05

- The median fluoroscopy time was also significantly lower in the MediGuide Technology group for the different indications (atrial flutter, AVNRT, WPW) when compared to the conventional group (p < 0.05 vs. conventional group for all indications).
- The authors note that a fast learning curve exists when utilizing MediGuide Technology— after less than five procedures, an experienced operator can perform the entire procedure with less than 30 seconds of fluoroscopy time.

Key takeaway:

- Supraventricular tachycardia ablation procedures using MediGuide Technology can be safe, effective and dramatically reduce fluoroscopy.

Initial Experience in Ablation of Typical Atrial Flutter Using a Novel Three-dimensional Catheter Tracking System

Sommer, et al. *Europace*, 2013⁸

- This study reports on the first clinical experience for ablation of cavo-tricuspid isthmus (CTI) dependent flutter using MediGuide Technology (n = 10).
- Coronary sinus cannulation was performed using two steerable diagnostic EP catheters and cavo-tricuspid isthmus reconstruction was performed with the EnSite™ Velocity™ system.
- Ablation was performed with a conventional 8 mm tip ablation catheter.
- In 10 out of 10 (100%) patients, both sensor-equipped catheters could be tracked non-fluoroscopically.
- In nine out of 10 (90%) patients, the CS cannulation was performed using the MediGuide Technology only.
- Complete isthmus block was achieved in all patients (100%).
- Mean procedure time was 55 ± 9 min.
- Mean fluoroscopy time was 2.5 ± 2 min with four patients (40%) obtaining fluoroscopy times of < 60 seconds.
- Mean fluoroscopy dose was 1355 ± 633 cGy/cm².

Key takeaways:

- In the first clinical electrophysiology application of the MediGuide™ System, the authors found the system to be stable and enabling excellent 3-D orientation for catheter positioning based on pre-recorded cine loops.
- The MediGuide Technology allowed for non-fluoroscopic diagnostic catheter tracking and short fluoroscopy times.

Ablation of Atrial Fibrillation Using Novel 4D Catheter Tracking within Auto-registered LA Angiograms

Rolf, et al. *Circulation: Arrhythmia and Electrophysiology*, 2012⁹

- This study assessed the feasibility of non-fluoroscopic catheter manipulation within dynamic LA chamber models and evaluated the integration of the MediGuide Technology into an established electroanatomical mapping system (n = 98).
- 49 patients received an AF ablation using the MediGuide Enabled™ EnSite™ Velocity™ System, another 49 patients received AF ablation with the conventional EnSite Velocity system.
- Catheter ablation was done without MediGuide Technology.
- Catheter deployment within the pre-acquired cine loops was successful in 45 of 49 (92%) of patients.
- Median total fluoroscopy time and mean radiation dose were significantly reduced with MediGuide Technology, with similar mean total procedure times (see table).

AF Ablation Procedures	MediGuide (n = 49)	Conventional (n = 49)	P-value
Total procedure time (min)	174 ± 43	157 ± 51	p = 0.06
Total fluoroscopy time (min)	16 [10, 23]	31 [25, 43]	p < 0.001
Radiation dose (cGy·cm ²)	7363 ± 5827	14453 ± 7403	p < 0.001

Key takeaways:

- For 49 of 49 patients (100%), catheter tracking within dynamic LA angiograms allowed nearly non-fluoroscopic creation of EnSite™ Velocity™ System geometries with subsequent CT model registration.
- MediGuide™ Technology significantly reduced fluoroscopy time and mean radiation dose during mapping and AF ablation procedures.

SUPPORTING DATA FROM SCIENTIFIC ABSTRACTS AND CLINICAL CASE REPORTS DEMONSTRATING FLUOROSCOPY REDUCTION WITH MEDIGUIDE™ TECHNOLOGY IN EP PROCEDURES

Non-fluoroscopic Sensor-based Catheter Navigation in Ablation of Atrial Fibrillation: A Randomized Comparison with Electroanatomic Standard Procedures

Rolf, et al. 2015 ESC Congress, EHRA Europace and HRS Annual Scientific Sessions [abstract]¹⁰⁻¹²

- This abstract reported preliminary outcomes from a single-center randomized comparison of standard AF ablation procedures performed by experienced operators using conventional electroanatomic mapping systems and fluoroscopy for catheter navigation, with or without MediGuide Technology non-fluoroscopic sensor tracking within pre-recorded X-ray loops.
 - A total of 80 patients (44 with paroxysmal AF) were randomized equally into the two groups.
- Procedural parameters and preliminary six-month follow-up clinical success (freedom from any atrial tachycardia or AF > 30 sec) are summarized in the table.

AF Ablation Procedures	MediGuide (n = 40)	Conventional (n = 40)	P-value
Total procedure duration (min)	136 ± 43	138 ± 51	p = 0.84
Radiofrequency time (min)	38 ± 16	39 ± 19	p = 0.80
Add. substrate modification	6 (15%)	9 (23%)	p = 0.57
Total fluoroscopy time (min)	3 ± 3	14 ± 6	p < 0.001
Fluoroscopy dose (Gy·cm ²)	687 ± 665	1899 ± 1396	p < 0.001
Periprocedural complications	0	0	p = 1.00
Success rate over 6 months	22/30 (73%)	18/22 (82%)	p = 0.53

- Total fluoroscopy time and dose were significantly reduced in the procedures using the MediGuide™ Technology (p < 0.001).
- Overall procedure duration and radiofrequency time were comparable between the two groups.
- Preliminary data for 52 of the 80 patients show no significant differences in six-month success rates for these procedures (p = 0.53).

Key takeaway:

- With experienced operators, radiation exposure following transeptal puncture can be almost completely abandoned by using the MediGuide Technology in addition to standard AF ablation technologies, without significant impact on overall procedure duration or clinical success rates.

Initial Experience in Pediatric Supraventricular Tachycardia Ablation with a New Sensor-based Three-dimensional Navigation System

Pilcher, et al. 2015 HRS Annual Scientific Sessions [abstract]¹³

- This abstract reports the first pediatric ablation series using MediGuide Technology sensor-enabled catheters in pre-recorded fluoroscopy cine-loops integrated into the EnSite™ Velocity™ 3-D mapping system.
- Consecutive pediatric SVT ablation cases (n = 38, ages 12 ± 4 years) were performed utilizing MediGuide Technology with non-fluoroscopic 3-D mapping (MG).
 - MediGuide Technology cases consisted of 12 AVNRT, 15 WPW, 7 AVRT and 3 AET.
- Procedure details were compared to procedures performed with 3-D mapping with fluoroscopy (FL) (n = 134) or non-fluoroscopic (NFL) (n = 168).
- Acute procedure success rates were similar in the three groups (97% with MediGuide Technology).
- While total procedure times were similar in all groups, fluoroscopy and mapping times were significantly shorter with MediGuide Technology than with FL, but not versus NFL (see table).

Pediatric SVT Ablation	MG Group (n = 38)	FL Group (n = 134)	P-value vs. MG	NFL Group (n = 168)	P-value vs. MG
Median total procedure time (min)	154	164	p = 0.5	175	p = 0.5
Median fluoroscopy time (min)	0.4	10.4	p < 0.001	0	p = 0.04
Median radiation dose (μGy·m ²)	40	303	p < 0.001	0	p < 0.001
Median mapping time (min)	18	34	p < 0.003	23	p = 0.2
Median number of test lesions	1	4	p < 0.004	2	p = 0.03

- The median number of test lesions before success was significantly less with MediGuide™ Technology than FL or NFL.

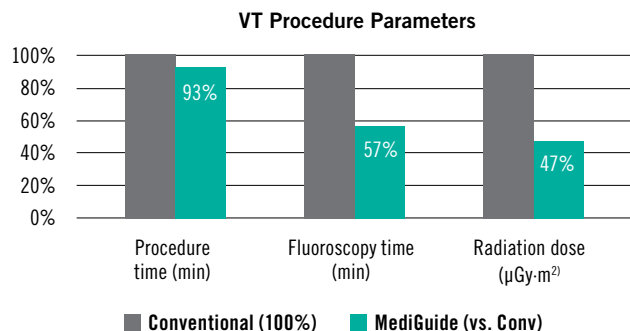
Key takeaways:

- MediGuide Technology required minimal radiation exposure (comparable to “non-fluoroscopic” ablation with the EnSite™ Velocity™ 3-D mapping system) and resulted in a substantial reduction in radiation exposure compared to conventional fluoroscopic ablation in pediatric patients.
- The MediGuide™ System improves accuracy of the EnSite Velocity 3-D mapping system resulting in fewer test ablations and a trend toward shorter procedure time.

Clinical Experience Using a New Fluoroscopy-integrated Catheter Tracking System (MediGuide) for Ablation of Ventricular Tachycardia-A Case Matched Comparison

Martinek, et al. 2015 HRS Annual Scientific Sessions [abstract]¹⁴

- This abstract describes a safety and feasibility assessment of the MediGuide System versus a conventional 3-D system for RF ablation of ventricular tachycardias (VT) in patients with structural heart disease (SHD) or idiopathic VT.
- A total of 63 consecutive VT cases were retrospectively compared in a 2:1 case-matched comparison:
 - SHD was noted in 13 patients (61.9%) in the MediGuide Technology group vs. 23 patients (54.8%) in the conventional group.
 - Idiopathic VT was noted in eight (38.1%) MediGuide Technology patients vs. 19 (45.2%) conventional patients.
- Approximately half of the patients had a history of recurrent ICD/CRTD shocks (n = 10 MediGuide Technology, 47.6% vs. n = 25 conventional, 59.5%).
- Mean fluoroscopy time (15 ± 8.39 vs. 8.6 ± 3.83 minutes, p = 0.0001) and radiation dose (3,733 ± 3,429 vs. 1,747 ± 1,770 μGy·m², p = 0.008) were significantly reduced by the use of MediGuide Technology (see figure).
- Mean procedure duration using MediGuide Technology was reduced by 16 minutes (not significant).



- In the MediGuide Technology group, 54.5% of the fluoro time and 58.3% of fluoro dosage was acquired in non-MediGuide Technology-dependent situations (positioning of conventional reference catheters, performing transseptal punctures).

Key takeaway:

- The use of the MediGuide System in VT ablation in an integrated 3-D environment (NavX) is feasible and safe, significantly reducing fluoro time and radiation dose compared to conventional 3-D systems.

Clinical Outcome of Ventricular Tachycardia Ablation Using a Novel 3D Cardiovascular Navigation System

Roth, et al. 2013 *European Heart Journal* [abstract].¹⁵

- In this study, MediGuide Technology was used as a navigation tool in VT ablation procedures (n = 14).
- Overall median fluoroscopy time was 4.0 minutes compared to 32.4 minutes from the institution’s published in-house data; overall median radiation dose was 2760.5 μGy·m².

Key takeaway:

- This study shows that using the MediGuide System as a navigation tool in complex VT ablation procedures may help reduce the duration of live X-ray in patients, physicians and medical staff.

“Conventional” Isthmus Ablation without Fluoroscopy

Sommer, et al. *Journal of Interventional Cardiac Electrophysiology*, 2013¹⁶

- This case report presents the University of Leipzig’s first experience in atrial flutter ablation using MediGuide Enabled ablation catheters.
- A 69-year-old male was admitted with typical atrial flutter for isthmus ablation.
- Total procedure time from acquisition of the cine loops to withdrawal of the sheaths was 45 minutes, with an overall fluoroscopy time of 6 minutes and a radiation dose of 32 cGy·cm².
- No further fluoroscopic support was used following the acquisition of the two cine loops.

Key takeaway:

- MediGuide™ Technology seamlessly allows for non-fluoroscopic catheter visualization within the workflow of conventional invasive electrophysiology procedures.

Atrial Flutter Ablation Using MediGuide Non-fluoroscopic Catheter Tracking System: A Novel Technology to Reduce Radiation Exposure

Pillai, et al. *Journal of Atrial Fibrillation*, 2012¹⁷

- This case report describes the first use of MediGuide Technology for the ablation of a typical right atrial flutter in North America (n = 1).

Key takeaways:

- Total fluoroscopy time was 3 minutes.
- The patient tolerated the procedure well and was discharged the next day.

Nonfluoroscopic Sensor-Guided Navigation of Intracardiac Electrophysiology Catheters within Prerecorded Cine Loops

Piorkowski, et al. *Circulation: Arrhythmia and Electrophysiology*, 2011¹⁸

- This study reports on the first-in-human application of the MediGuide System for 3-D EP catheter tracking in full integration with conventional fluoroscopy imaging (n = 1).
- The study tested clinical feasibility, stability and accuracy of the guided medical positioning system to perform non-fluoroscopic right and/or left atrial catheter positioning in patients presenting for diagnostic EP procedures and supraventricular tachycardia ablation.

Key takeaways:

- All catheters were positioned entirely non-fluoroscopically at the intracardiac location.
- Total fluoroscopy time was 30 seconds; radiography was only used for initial cine loop acquisition and for confirmation of catheter position.

MEDIGUIDE™ TECHNOLOGY ACCURATELY AND RELIABLY TRACKS SENSOR-ENABLED TOOLS FOR CRT LEAD PLACEMENTS

MediGuide Technology is an electro-magnetically guided navigation system that is used as an adjunct to fluoroscopy. It uses a pre-recorded cine loop and reduces the fluoroscopy time and exposure to patients, physicians and staff. The studies summarized in the table below and on the following pages support the accuracy of MediGuide Technology to track catheters and significantly reduce the use of fluoroscopy during coronary sinus (CS) cannulation and left ventricular (LV) lead placement in CRT device implant procedures.

Summary of Peer-Reviewed Published Clinical Data with MediGuide™ Technology in CRT Device Implant Procedures

Study, Year	Study Type	Procedure Type(s)	Fluoroscopy Time / [Total Procedure Time, if reported] (no. of patients per group)			Radiation Dose			Acute Procedural Success	Complications
			MediGuide	Conventional	P-value	MediGuide	Conventional	P-value		
Döring, 2015 ¹⁹	Single-center series of consecutive implants (n = 71); matched cohort analysis (n = 68)	CRT device implants (n = 71)	4.9 min [87 min] (n = 71)	NA	NA	476 µGy·m ²	NA	NA	100%	No serious complications related to implant procedure
		CRT device implants (n = 68)	4.5 min [71 min] (n = 34)	8.0 min [67 min] (n = 34)	< 0.001 [0.066]	338 µGy·m ²	603 µGy·m ²	< 0.001		
Thibault, 2015 ²⁰	Prospective, non-randomized, single-center cohort study of consecutive patients	CRT device implants (n = 130)	6.5 min [120 min] (n = 60)	19.1 min [138 min] (n = 70)	< 0.001 [0.088]	769 µGy·m ²	2608 µGy·m ²	< 0.001	94.6% (combined)	MediGuide: CS cannulation failure (n = 1), lead implantation failure (n = 2) Conventional: CS cannulation failure (n = 1), lead implantation failure (n = 3), pocket hematoma (n = 3)
Richter, 2013 ²¹	Non-randomized, single-institution series	CRT device implants (n = 15)	5.2 min [116 min] (n = 15)	NA	NA	Not reported	NA	NA	100%	No severe adverse events

Sensor-based Electromagnetic Navigation to Facilitate Implantation of Left Ventricular Leads in Cardiac Resynchronization Therapy

Döring, et al. *Journal of Cardiovascular Electrophysiology*, 2015¹⁹

- This study from Leipzig analyzed procedural data for a total of 71 consecutive patients implanted with CRT devices over a two-year period using the MediGuide™ System, including the Angio Survey™ 2-D Fusion to facilitate lead positioning.
- Non-fluoroscopic CS intubation with pre-recorded cine-loops was possible in 63 patients (89%), and LV lead implantation was successful in all patients with no severe adverse events.
- Total procedure time measured 87 ± 37 minutes, and median total fluoroscopy time (skin-to-skin) was 4.9 (2.5–7.8) minutes.
- Median radiation dose was 476 (260–1056) cGy·cm².
- In a comparison of a matching cohort of 34 patients with conventional CRT device implantations, MediGuide™ Technology implants were associated with a significant reduction in fluoroscopy time and radiation dose (see table).

CRT Implants	MediGuide (n = 34)	Conventional (n = 34)	P-value
Total procedure time (min)	71 (60-85)	67 (55-78)	p = 0.066
Non-fluoro CS Intubation (%)	85	0	p < 0.001
Total fluoroscopy time (min)	4.5 (2.8-7.3)	8.0 (5.8-11.5)	p = 0.016
Radiation dose (cGy·cm ²)	338 (176-680)	603 (330-969)	p = 0.044

- Substantial reductions in fluoroscopy and operation times, as well as radiation exposure, were also seen over time with increasing operator experience and improvements in the MediGuide Technology.

Key takeaway:

- The MediGuide System enables safe and successful LV lead placement with significantly reduced radiation exposure during CRT implantation.

Reducing Radiation Exposure during CRT Implant Procedures: Early Experience with a Sensor-Based Navigation System

Thibault, et al. *Pacing and Clinical Electrophysiology*, 2015²⁰

- This article provides a comparison of ionizing radiation (IR) exposure during CRT implant procedures guided by the MediGuide System vs. without the use of the MediGuide System (n = 60 and n = 70, respectively).
- As shown in the table below, the MediGuide System was associated with a statistically significant reduction of 66% in total IR exposure (p < 0.001), which was driven by a > 90% reduction in IR time and dose required for cannulating the coronary sinus (p < 0.001).
- In addition, there was a statistically significant 71% reduction in IR dose (69% reduction when adjusted for BMI) when using the MediGuide System (p < 0.001).

	Non-MediGuide™ Technology	MediGuide™ Technology	P-value
Median total IR exposure time (minutes)	19.1	6.5	p < 0.001
Median IR exposure dose (μGy·m ²)	2608	769	p < 0.001
Median IR exposure dose/BMI (μGy·m ² /kg/m ²)	92.2	28.2	p < 0.001

- For CRT implants guided by the MediGuide System, the overall procedure time was not significantly different (120 minutes vs. 138 minutes, P = 0.088)
- However, a statistically significant reduction in the median total procedural time was shown between the first 15 and last 15 cases (175 minutes vs. 98 minutes, respectively, p < 0.001).

Key takeaways:

- The use of the MediGuide System is associated with a reduction in total IR exposure time and dose during CRT implantation.
- A reduction in the median total procedure time using the MediGuide System was associated with increased operator experience.

Cardiac Resynchronization Therapy Device Implantation Using a New Sensor-based Navigation System: Results from the First Human Use Study

Richter, et al. *Circulation: Arrhythmia and Electrophysiology*, 2013²¹

- In this single-center study, a total of 15 patients had LV leads successfully implanted and were followed for four weeks.
- Total procedure time was 116 ± 43 minutes; median total fluoroscopy time (skin to skin) was 5.2 minutes, while fluoroscopy time for LV lead placement was 2.6 minutes.
- Median radiation exposure for LV lead implantation (CS cannulation to final LV lead placement) was 9.2 Gy·cm² (Q1-Q3 6.1-16.2).
- No fluoroscopy was used to cannulate the CS in 80% (12/15) of the cases.

Key takeaway:

- This first human use study demonstrates that the MediGuide System allows for successful CRT implantation with the potential for reduced duration of fluoroscopy.

SUPPORTING DATA FROM SCIENTIFIC ABSTRACTS AND CLINICAL CASE REPORTS USING MEDIGUIDE™ TECHNOLOGY IN CRT DEVICE IMPLANT PROCEDURES

Resynchronization Therapy Implant Procedures with a Novel Sensor-based Electromagnetic Tracking System: More than Just Reduction in Radiation Exposure

Thibault, et al. 2015 EHRA Europace [abstract]²²

- This abstract reports on a large series of 217 CRT device implant procedures performed since the introduction of the MediGuide™ System at the Montreal Heart Institute.
- Use of MediGuide System for CS cannulation and LV lead placement resulted in significant reduction in total procedure duration, total radiation time and total radiation dose compared to contemporary non-MediGuide procedures (see table).

CRT Implants	MediGuide (n = 161)	Non-MediGuide (n = 56)	P-value
Total procedure duration (min)	109 ± 40	127 ± 46	p = 0.012
Total radiation time (min)	8.2 ± 9.9	25.8 ± 16.9	p < 0.001
Radiation dose (μGy·m ²)	1164 ± 1531	5048 ± 9221	p < 0.001

- Failure to implant the LV lead was noted in 6/161 (3.7%) with MediGuide Technology vs. 7/56 (12.5%) non-MediGuide Technology procedures (p < 0.001).
- A learning curve was evident from a comparison of the first 20 cases and the last 20 cases with the use of the MediGuide™ Technology.
 - Total procedure time was shorter in the last 20 cases: 85 ± 31 vs. 171 ± 34 min (P < 0.001)
 - Radiation time was also shorter in the last 20: 4.5 ± 4.0 vs. 10.3 ± 7.1 min (p = 0.004)
 - Radiation dose was lower in the last 20 cases: 627 ± 982 vs. 1,802 ± 1,621 μG·m² (p = 0.009)

Key takeaway:

- This large series confirms the benefits of the MediGuide Technology virtual biplane imaging system noted in earlier series, with significant reductions in radiation exposure (time and dose) – as well as shorter CRT device implant procedure times compared to contemporary non-MediGuide Technology implants.

Left Ventricular Lead Implantation Guided by Sensor-based Electromagnetic Navigation in a Patient with L-transposition of the Great Arteries

Richter, et al. *European Heart Journal*, 2014²³

- The authors report on the use of MediGuide Technology to guide LV lead placement in a 31-year-old male with a congenital heart defect (n = 1).
- Echocardiography revealed dilatation of the systemic RV, reduced RV ejection fraction (45%), moderate tricuspid regurgitation, and signs of ventricular dyssynchrony.
- The patient was upgraded from a dual-chamber pacemaker to an implantable ICD with biventricular pacing; non-fluoroscopic intubation of the coronary sinus and subselection of the target vein was achieved with MediGuide Technology.

Key takeaway:

- MediGuide Technology helps guide LV lead placement and increases spatial anatomic orientation during CRT procedures in patients with complex cardiac and CS venous anatomy.

SUPPORTING DATA FROM ANIMAL, PHANTOM MODEL AND INITIAL HUMAN STUDIES DEMONSTRATING MEDIGUIDE™ SYSTEM ACCURACY AND FLUOROSCOPY REDUCTION

3D Cardiovascular Navigation System: Accuracy and Reduction in Radiation Exposure in Left Ventricular Lead Implant

Valderrabano, et al. *Journal of Cardiovascular Electrophysiology*, 2014²⁴

- This was a preclinical study involving six canines; data were collected by three different implanters in three standard fluoroscopic projections (RAO, LAO, AP) and at three different heart rates (60 to 140 bpm).
- There was no significant difference in LV lead delivery time between the implants guided by the MediGuide™ System and conventional implants (233 ± 195 vs. 186 ± 177 seconds, $p = 0.27$).
- Mean fluoroscopy time and radiation exposure were significantly lower for implants guided by the MediGuide System compared to conventional implants:
 - ~ 60% less fluoroscopy time: 52 ± 120 vs. 129 ± 118 seconds, $p < 0.001$
 - ~ 72% reduced radiation exposure: 13.8 ± 32.4 vs. 49.2 ± 45.3 $\mu\text{Gy}\cdot\text{m}^2$, $p = 0.03$
- Overall median displacement accuracy was 0.48 ± 0.94 mm from the target branch; median separation was 0.00 mm.
 - System accuracy was not affected by various C-arm angulations. RAO was 0.36 ± 0.82 mm, LAO was 0.48 ± 0.93 mm, and AP was 0.59 ± 1.04 mm.
 - System accuracy was also unaffected by heart rate variations up to ± 30 bpm from the original heart rate that was used to acquire the CS venogram.

Key takeaway:

- This article demonstrates the accuracy of MediGuide™ Technology in a lab environment to successfully guide and place LV leads with a significant reduction of the fluoroscopy time and no impact on procedure times.

Sensor-Based Electromagnetic Navigation (MediGuide): How Accurate Is It? A Phantom Model Study

Bourier, et al. *Journal of Cardiovascular Electrophysiology*, 2015²⁵

- In Munich, a realistic heart phantom model was generated using a 3-D printer and a CT scan was performed as a ground-truth reference to determine accuracy and reproducibility of MediGuide Technology catheter placement using the EnSite™ Velocity™ system.
- Point localization accuracy was 0.5 ± 0.3 mm for MediGuide Technology and 1.4 ± 0.7 mm for the EnSite Velocity system.

- The 3-D accuracy of the acquired geometries was 1.1 ± 1.4 mm (MediGuide-scaled) and 3.2 ± 1.6 mm (not-MediGuide-scaled).
- The offset between virtual MediGuide™ System catheter visualization and catheter representation on corresponding fluoroscopic cine-loops was 0.4 ± 0.1 mm.

Key takeaways:

- The MediGuide Technology offers highly accurate point localization and spatial accuracy, as well as highly accurate catheter visualization on fluoroscopy image.
- The observed offsets between the virtual 3-D visualization and the real phantom were below a clinically relevant threshold.
- The MediGuide System provides high enough accuracy to reliably guide EP procedures, so that the additional use of fluoroscopy may be reduced or eliminated.

Dynamic 3D Model of Coronary Sinus Anatomy Utilizing 3D Cardiovascular Navigation System

Greenberg, et al. *Cardiostim* 2012 [abstract]²⁶

- This study reported on the ability of the MediGuide System to accurately model CS anatomy by performing contrast-enhanced venography at four C-arm orientations on a sedated canine ($n = 1$).
- Automatic computation of dynamic 3-D models over a cardiac cycle using the MediGuide System Angio Survey™ feature from both LAO and AP views were performed.

Key takeaway:

- Results showed that differences between the MediGuide System Angio Survey 3-D feature CS model vs. reference venogram did not exceed 0.5 mm. LAO 40 was 0.1 ± 0.06 mm while AP was 0.2 ± 0.14 mm, confirming that the Angio Survey 3-D feature allows for sub-millimeter accurate construction of CS models.

MediGuide Technology Robustly and Accurately Tracks Catheter Location

Sih, et al. *Heart Rhythm*, 2012²⁷

- Swine were used to test the accuracy of the MediGuide System ($n = 4$).
- After obtaining baseline cines, diagnostic and ablation catheters with MediGuide Enabled™ sensors were positioned in several locations within the heart.

Key takeaway:

- Results showed that MediGuide Technology accurately tracks real-time catheter location even when real-time heart and respiratory rates have changed.

First-in-man (FIM) Experience with the Magnetic Medical Positioning System (MPS) for Intracoronary Navigation

Jeron, et al. *EuroIntervention*, 2009²⁸

- This study investigated the safety and feasibility of the MediGuide™ System for intracoronary tracking (n = 20).
- Performance was evaluated on a scale of 1 to 5; 5 indicated excellent superimposition with the vessel, while a score of 1 was given to assessments that had unacceptable performance.
- The mean score for tracking by projection on live fluoroscopy was 4.89 vs. 3.58 by projection on recorded cine-loop.

Key takeaways:

- Length measurement of a 20 mm distance was significantly better with the MediGuide System (mean deviation of 0.6 mm = 3%) vs. standard tracking system (1.5 mm = 8%, $p < 0.05$).
- No adverse events occurred; 3-D reconstruction was possible in 13 out of 20 cases (65%) with an average score of 4.68.

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Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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