



**THE CONFORM PIVOTAL TRIAL -
AN EVALUATION OF THE SAFETY AND EFFECTIVENESS OF THE
CONFORMAL CLAAS SYSTEM FOR LEFT ATRIAL APPENDAGE
OCCLUSION**

CT ACQUISITION PROTOCOL

Revision A

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APPROVAL SIGNATURE

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The undersigned hereby jointly declare that they have reviewed the CT Acquisition Protocol, understand the impacts associated with approving this Protocol, and agree to its form and content.

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1 Purpose

The purpose of this protocol is to provide recommendations on CT data acquisition and reconstruction for the cardiac CT performed for the CONFORM Pivotal Trial sponsored by Conformal Medical Inc. The CT data may be used in the screening process to assess inclusion / exclusion criteria and subject suitability for enrollment. CT follow-up imaging provides information on device positioning, residual LAA perfusion and thrombotic appositions.

2 Scope

This protocol is limited to the aspects of the CT data acquisition.

3 Scanner Requirements

The CT exam must be performed using a multi-detector scanner with at least 64-detector rows.

4 CT Data Acquisition/Protocol Fundamentals

The CT examination should be comprised of two main elements. An ECG-assisted contrast enhanced cardiac CT scan covering the entire heart and including the entire LAA and a delayed phase ECG-assisted acquisition limited to the LAA. The latter serves the purpose to increase the specificity for LAA thrombus detection, in particular by decreasing false positive findings.

The following lists the main components to create a default protocol.

4.1 Preparation

- Placement of an IV access in an antecubital vein (an 18-gauge IV typically provides the highest safety).
- Positioning of the patient on the scanner table in supine position; positioning should be similar to patient positioning on the cath lab/hybrid OR table, although arms are routinely elevated above the head to reduce radiation absorption at the level of the cardiac structures.
- Placement of ECG-electrodes for subsequent ECG-assisted data acquisition
- Patient instruction on breath-holding to improve patient compliance

Beta-blockers can be considered in patients with a resting heart rate >75 beats per minute. Administration of beta-blockers must be in accordance with the institutional local guidelines. Contraindications to beta-blockers have to be considered. In patients with contraindications to beta-blockers alternative rate controlling medications may be used

4.2 Scouts (Topogram, Scanogram)

- Standard AP, plus lateral scouts (depending on the scanner system) of the thorax

4.3 Contrast administration

Contrast administration protocols should allow for sufficient contrast opacification of the left atrium and left atrial appendage. The delayed phase acquisition does require an additional contrast administration.

- **Bolus tracking:** In general, ‘bolus tracking’ is recommended to trigger data acquisition. The region of interest (ROI) for bolus tracking should be placed within the ascending aorta for 64/128/192 detector row scanners (all scanners except GE Revolution and Toshiba Aquilion One) or in the left atrium for volume scanners (GE Revolution and Canon/Toshiba Aquilion One). The threshold to trigger data acquisition has to be selected while taking into account the time needed for automated breathing instructions and a potential pre-scan delay, with the aim to achieve sufficient contrast enhancement in the left atrium.
- **Contrast injection:** Contrast administration requires the use of a dual-head injector and is performed as a biphasic protocol, i.e. injection of non-diluted contrast followed by a saline chaser. The amount of contrast and injection time should be adjusted to the patient’s body habitus and the scanner system and scan time. Iodine delivery rate (mg/sec) has to be increased in patients with larger body habitus. This can be achieved using higher flow rates. Commonly used rates are 60-90ml contrast media at 3.5-4cc/sec (depending on iodine concentration and body habitus), followed by 50cc saline at the same injection rate.

4.4 First-pass ECG-assisted contrast enhanced cardiac CT data acquisition (‘ First-pass Cardiac CT’)

An ECG-assisted contrast enhanced CT data acquisition of the entire heart including the entire LAA is required in all patients in order to assess the cardiac structures.

- **Acquisition modes:** With all scanner types/vendors, data acquisition should be performed using axial/sequential, prospective ECG-triggering. Depending on the scanner geometry, data acquisition is either performed as a ‘step&shoot’ acquisition or as a gated ‘one beat whole heart’ acquisition (volume scanners).

Manufacturer	Scanner Geometry	Acquisition mode
GE	64-row family (750HD, Discovery)	Step&Shoot (prospective ECG-triggering; axial/sequential)

	Revolution (256 row)	Gated one beat acquisition (prospective ECG-triggering; axial/sequential)
Philips	All scanners	Step&Shoot (prospective ECG-triggering; axial/sequential)
Siemens	All scanners	Step&Shoot (prospective ECG-triggering; axial/sequential) Dual Source scanners: High-pitch helical
Canon/Toshiba	64/80-row family	Step&Shoot (prospective ECG-triggering; axial/sequential)
	Aquilion One	Gated one beat acquisition(prospective ECG-triggering; axial/sequential)

- **Tube and detector settings:** Tube voltage and tube current settings should reflect settings of routine cardiac CT protocols and should follow institutional guidelines. For LAA imaging, higher image noise and thus lower mAs/mA levels are acceptable compared to coronary cardiac CT. Tube voltage should be BMI adjusted.
- **Scan length:** The scan range should extend from the tracheal bifurcation to at least 2cm below the left ventricular apex and has to include the entire LAA. CAVEAT: The routine approach of starting 2cm below the carina for coronary cardiac CT may sometimes lead to incomplete imaging of the LAA.
- Axial/sequential data acquisition (Step&Shoot) should be performed in cranial to caudal direction. Data should be acquired at the smallest available collimation (ideally <0.75mm), based on individual system capabilities.
- **Cardiac cycle coverage:** The target phase for ECG-assisted imaging is end-systole. Common approaches for end-systolic imaging included target phases of e.g. 35% of the RR-interval or 300msec past R-peak.

4.5 Delayed phase ECG-assisted CT data acquisition of the LAA

An ECG-assisted delayed phase CT data acquisition, limited to the LAA should be performed in all patients immediately following the cardiac data acquisition to provide further image data for evaluation of LAA. This data acquisition does not involve additional contrast media administration.

- **Scan mode:** Identical scan mode as use for first-pass cardiac CT.
- **Scan length:** The scan length should cover the LAA but does not have to cover the entire left ventricle.

- **Cardiac cycle coverage:** Identical target phase as for the first-pass cardiac CT.

5 CT Data reconstruction

The first-pass and delayed phase ECG-assisted cardiac CT data sets should be reconstructed as follows

- Axial, thin sliced reconstructions, $\leq 1\text{mm}$; e.g. 0.6mm, 0/4mm increment
- Field of View (FoV) limited to the heart.
- Filtered-back projections or iterative reconstructions using a soft tissue convolution kernel/filter