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HeartPrint® Imaging Guidelines

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These general HeartPrint® imaging guidelines can help you reach the optimal image quality to create a HeartPrint® model. Should you have any questions or require further clarification, please don't hesitate to contact us via HeartPrint@materialise.com. We are happy to help you as well on more specific imaging guidelines for pediatric patients.

Computed Tomography (CT)

Heart Structures

(Examples: aortic and pulmonary valves, coronaries, LAA …)

General rule: standard ECG-triggered diastolic protocol with good contrast, more specifically:

- 100-120kV, 550-700mAs
- Slice distance: 0.3-0.7mm (0.5mm most common)
- Slices are incremental or (at least) equal to slice distance
- CT scanner with 64 or more slices to avoid motion and misalignment artifacts
- Medium contrast on the left or right side of the heart for diagnostic imaging
- Heartbeat below 65
- For the access route (if required): see vessel structure details below
- Ideally, with the patient holding their breath

Vessel Structures

(Examples: TAA, AAA, coarctation …)

General rule: standard vascular protocol with good contrast, more specifically:

- 100-120kV, 550-700mAs
- Slice distance: 0.7-1mm
- Slices are incremental or (at least) equal to slice distance
- CT scanner with 16 or more slices to avoid long scans
- No ECG triggering required
- Medium contrast on the left or right side of the heart for diagnostic imaging

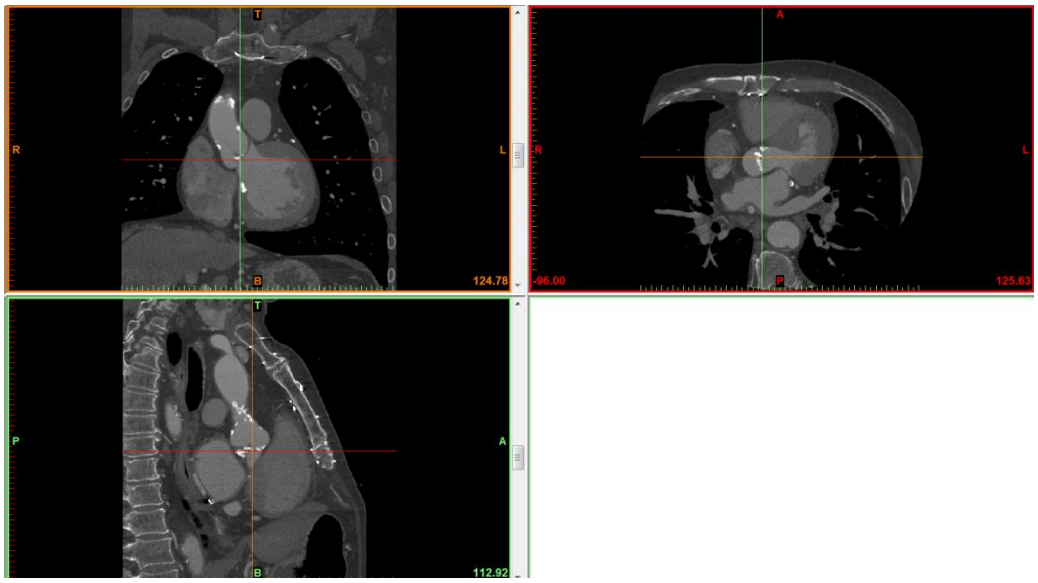

Figure 1. *Example of an approved CT heart scan – good scan with clear contrast, slice increment and slice distance 0.625mmm, no misalignments*

Magnetic Resonance Imaging (MRI)

Heart Structures

(Examples: aortic and pulmonary valves, coronaries, LAA …)

General rule: standard diastolic protocol with good contrast, more specifically:

- Slice distance: 0.3-0.7mm (0.5mm most common)
- Slices are incremental or (at least) equal to slice distance
- The higher the spatial resolution the better (as long as the signal-to-noise ratio permits)
- Ideally, with the patient holding their breath
- Contrast medium (e.g. Ablavar®) on the left or right side of the heart for diagnostic imaging
- For full heart: it is preferable to obtain 3D volume data (at least) three times and merge it into one file so that all cardiovascular structures contain contrast medium
- **Important rule:** nearly isotropic voxels (not standard)

Vessel Structures

(Examples: TAA, AAA, coarctation …)

General rule: standard vascular protocol with good contrast, more specifically:

- Slice distance: 0.7-1mm
- Slices are incremental or (at least) equal to slice distance
- The higher the spatial resolution the better (as long as the signal-to-noise ratio permits)
- Contrast medium (e.g. Abalavar®) on left or right side of the heart for diagnostic imaging
- **Important rule:** nearly isotropic voxels (not standard)

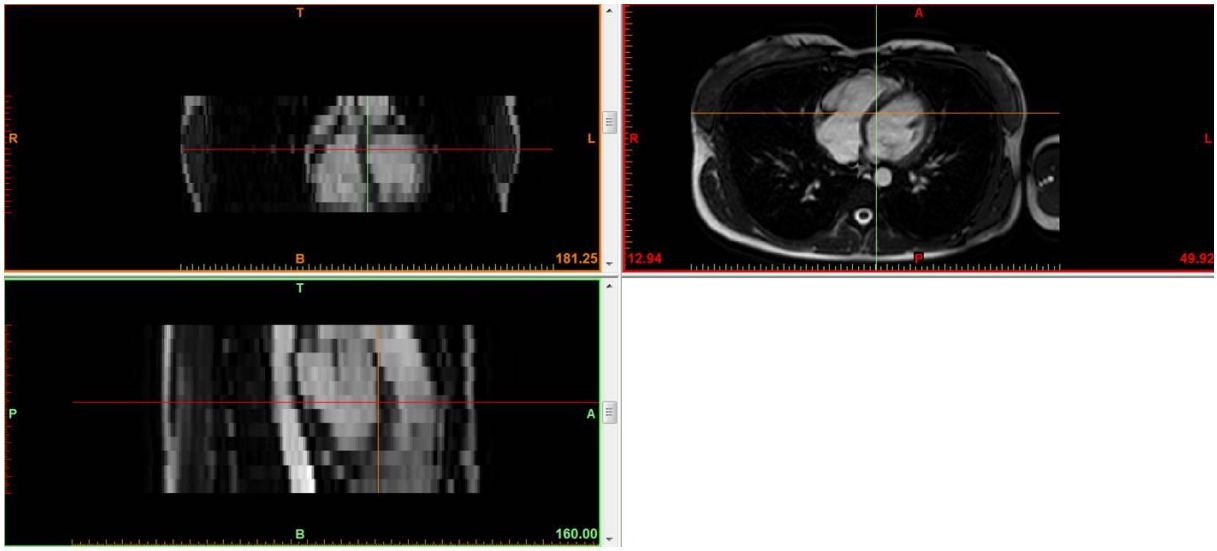

Figure 2. *Example of MRI heart unsuitable – very anisotropic voxels (large slice increment)*

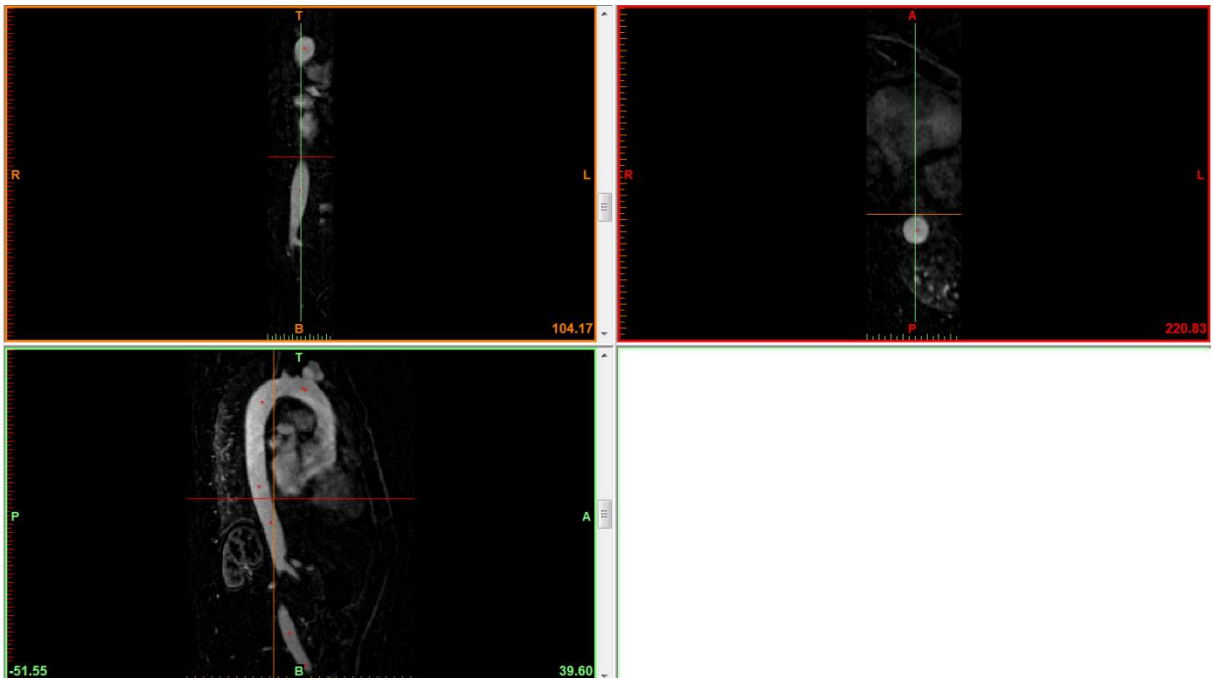

Figure 3. *Example of an approved MRI of an aorta: isotropic voxels, 0.9mm slice increment and thickness*

Regulatory Information:

The Medical edition of the Mimics® Innovation Suite currently consists of the following software components: Mimics® Medical version 17.0 and 3-matic® Medical version 9.0 (released 2014). Mimics® Medical is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also used as pre-operative software for simulating /evaluating surgical treatment options. 3-matic® Medical is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient-specific medical and dental/orthodontic accessories and dental restorations.

HeartPrint® is registered as a medical device in the USA and in the EU market. HeartPrint® models are intended to assist cardiovascular professionals in selecting appropriate tools and/or deciding on the optimal insertion of medical devices (such as stents), for cardiovascular surgical interventions.

The Research edition of the Mimics® Innovation Suite currently consists of the following software components: Mimics® Research version 17.0 and 3-matic® Research version 9.0 (released 2014). Mimics® Research is intended only for research purposes. It is intended as a software interface and image segmentation system for the transfer of imaging information from a variety of imaging sources to an output file. It is also used as software for simulating, measuring and modeling in the field of biomedical research. “Mimics® Research” must not be used, and is not intended to be used, for any medical purpose whatsoever. 3-matic® Research is intended for use as a software for computer assisted design and engineering in the field of biomedical research. “3-matic® Research” must not be used, and is not intended to be used, for the design or manufacturing of medical devices of any kind.

HeartPrint® Research models are not intended to be used as a medical device. Models cannot be sterilized and therefore cannot be taken into the surgical theatre.

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