SYNOPSYS®

Simpleware Medical

Software Solutions for Clinical Applications

FDA 510(k) cleared
CE marked
ISO 13485:2016 certified

3D Image Data Processing for Clinical Workflows with Simpleware Medical

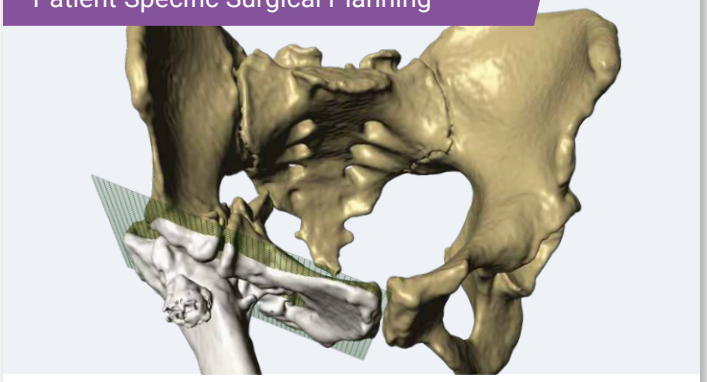
Tackle Clinical Imaging Challenges with Confidence

When working in a clinical setting, Simpleware Medical is the ideal choice for improving confidence in clinical decision-making and pre-surgical planning. Simpleware software provides powerful tools for creating virtual and physical 3D models from medical imaging data.

Simpleware Medical Provides the Following Benefits:

- Better understanding of patient anatomies through 3D model visualization and segmentation compared to 2D visualization
- Plan surgeries more effectively with virtual 3D models and 3D printed anatomical models
- Select the safest and optimal treatment (implant selection/ device sizing and customization) based on accurate measurements of patient anatomies
- Analyze past procedures and improve future ones by comparing pre-surgical plans with post-clinical images
- Improve clinical training and patient communication through patient-specific 3D models
- Lower risk of complications and improve recovery times
- Enhance functional and aesthetic surgical outcomes, and boost patient's psychological and physical recovery
- Lower the need for revision surgery

Patient-Specific Surgical Planning



Improve Confidence in Clinical Decision-Making

Integrating Simpleware Medical's 3D visualization and segmentation features into clinical workflows facilitates more efficient planning of surgical treatment, leading to better patient outcomes.

- Generate models from 3D image data to improve understanding of individual patient anatomies
- Perform measurements on anatomical data to assess surgical treatment options
- Improve confidence in pre-surgical plans with patient-specific 3D models
- Export models for further analysis

Point-of-Care 3D Printing

Anatomical 3D Printing for Better Surgical Planning

The extensive image processing and 3D printing tools available in Simpleware Medical enable the generation of high-quality 3D printed anatomical models with confidence.

- Print accurate, patient-specific models to practice and plan surgical procedures
- Improve anatomical understanding with realistic physical models
- Range of tools for preparing and reviewing models before export to 3D printing
- Use 3D printed models for communication, training, and to inform diagnostic decisions

Complete Solutions for 3D Medical Image Processing with Regulatory Compliance

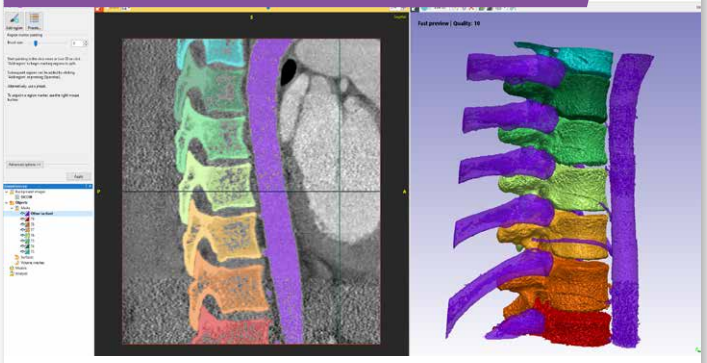
FDA, CE, and ISO Certified

Exceptional Software with Regulatory Compliance

Simpleware Medical comes with FDA 510(k) clearance, CE marking and ISO 13485:2016 certification as a medical device. Use Simpleware Medical as a software interface and image segmentation system for the transfer of medical imaging information to an output file.

- Developed for biomedical engineers to inform clinical management
- Speed up compliance processes by integrating certified software into your workflows
- Trust in software that has gone through rigorous compliance processes
- FDA-cleared for end-to-end diagnostic 3D printing with compatible printers

Complete Medical Image Processing Toolkit



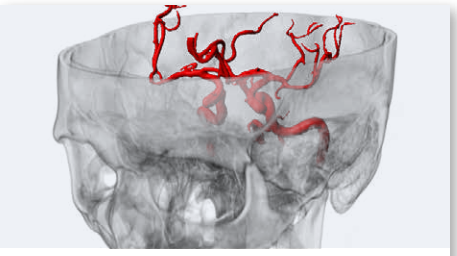
Explore Patient Anatomies to Optimize Outcomes

Simpleware Medical enables straightforward processing of patient-specific medical imaging. Visualize and segment anatomies, and perform advanced analyses using extensive measurement and statistics tools. Improve confidence in clinical decision-making through reliable anatomical models.

- Easy-to-use intuitive interface with quick-and-easy access to all tools and features
- Take advantage of exclusive features designed specifically for clinical applications
- Streamline software resources with a complete medical image processing platform
- Comply with privacy standards for handling patient data
- Comprehensive tutorials, integrated help and expert technical support

From Image Processing to Model Generation

Image Processing | **Auto Segmentation**



Import, Registration & Visualization

Import Modalities

- MRI
- CT
- Micro-CT
- Ultrasound
- 2D X-ray images

Registration Options

- Co-registration of multiple 2D and/or 3D datasets
- Store and manage DICOM tags
- Anonymization
- Compatible with PACS

Object Visualization

- 3D live mode for instant updates
- Range of 2D and 3D visualization options
- Overlay surface contours in 2D
- Interactive image reslicing with multiplanar reconstruction mode

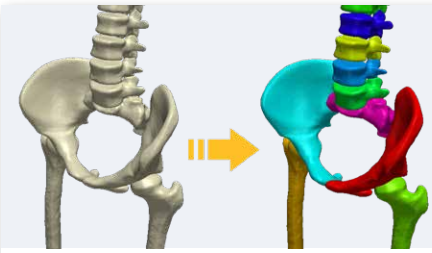


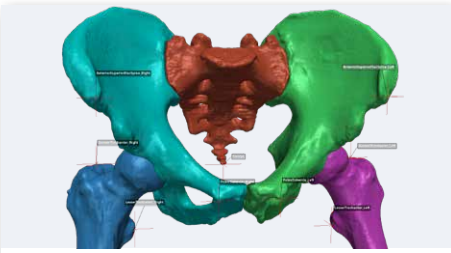
Image Processing

Image & Mask Filters

- Noise reduction
- Smoothing/morphological filters
- Align, rescale and resample
- Robust Boolean operations

Segmentation

- Threshold, floodfill and painting
- Interactive 3D editing tools
- Advanced region-growing tool
- Contour-based magnetic lasso
- Tools for handling poor contrast, artefacts and low quality data
- 3D wrap tool for scaffold-based segmentation
- Split tool to separate parts automatically
- Greyscale-based slide-to-slice propagation and interpolation
- Local surface correction to compensate for artefacts
- De-stepping



AI Segmentation & Landmarking*

Simpleware AI Models

- Ankle CT segmentation and landmarking
- CMF CT segmentation and landmarking
- Heart CT segmentation and landmarking
- Heart Valve analysis
- Hip CT & Hip Revision CT segmentation and landmarking
- Knee CT & MRI segmentation and landmarking (including cartilage for MRI)
- Shoulder CT segmentation and landmarking
- Spine CT segmentation

External AI Models

- Import and run externally trained AI models (MONAI Bundles, TotalSegmentator, Simpleware Bundles)

Have Confidence in your Models

Simpleware Medical is ideal for processing medical image data into 3D models for pre-surgical planning and 3D printing. Achieve reliable results for complex anatomical analysis using measurement and statistics tools. Take advantage of patient-specific 3D models to improve confidence in clinical decision-making and pre-surgical treatment plans.

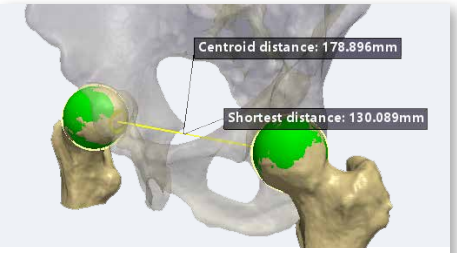
Customize your Workflow with Scripting

All functionality within Simpleware products is accessible from a fully documented API, with bindings available for Python and C#. Use this API to automate repeatable workflows, build wizards and integrate custom plugins. Use the macro recording functionality and generate code without any prior experience, accelerating routine tasks and scaling up workflows.

*For non-clinical research use only - not cleared for use as a medical device

From Image Processing to Model Generation

Measurements | Surface Tools | Volume Mesh Tools



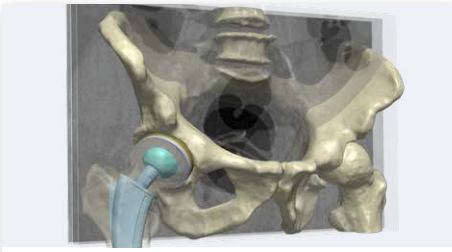
Measurements & Statistics

Interactive Tools

- Simple quick statistics and measurements
- Generate and probe centerlines networks
- 2D & 3D shape fitting and statistics
- Wall thickness analysis

Statistics Framework

- Thoroughly interrogate image data, generated models, or centerlines
- Extensive range of metrics
- Highly flexible for creating custom statistics templates
- Generate PDF reports describing your data



Accurate Models for Design & 3D Printing

3D Design & Image Integration

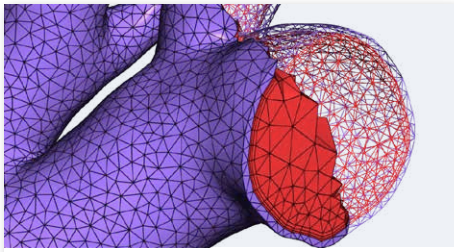
- Fast and easy-to-use tools to combine design and image data
- Import design files (STL, IGES, STEP...)
- Automatic snap or landmark-based registration

Cutting Guide Design & 3D Printing

- Design patient-specific bone cutting guides*
- Dedicated tools to cut, hollow, emboss text, create connectors...
- Export multiple formats designed for 3D printing

Models for Design

- Automatic NURBS patch fitting
- Highly accurate conversion for further design work or simulation
- Export as STEP or IGES



Simulation-Ready Models

- Conforming multi-part volume meshes
- Feature-based and user-defined mesh refinement
- Per-part meshing controls
- Define contacts and node sets
- Hounsfield material mapping for FE exports
- Boundary layer meshing
- Dedicated native exports for all major solvers
- Optimize element qualities against a choice of metrics
- Import existing meshes and assign material properties
- Segmentation checker to identify and fix problematic regions before meshing
- Mesh quality histogram to inspect generated mesh

Integrate Image and Design Data

Combine computer-aided design (CAD) models with 3D image data within the Simpleware software environment to capture patient-specific anatomical details whilst maintaining the design features of the CAD data. Improve understanding of individual patient anatomies, including selection of safest and optimal treatments (implant choice/device sizing/customization).

From Image to Mesh

Simpleware Medical offers a direct route from image data to a variety of output formats for design, simulation and 3D printing, making it possible to evaluate virtual models as part of clinical decision-making. Generated meshes are ready to use in the FE/CFD solver of your choice, with extensive options for tailoring your models to different simulation requirements.

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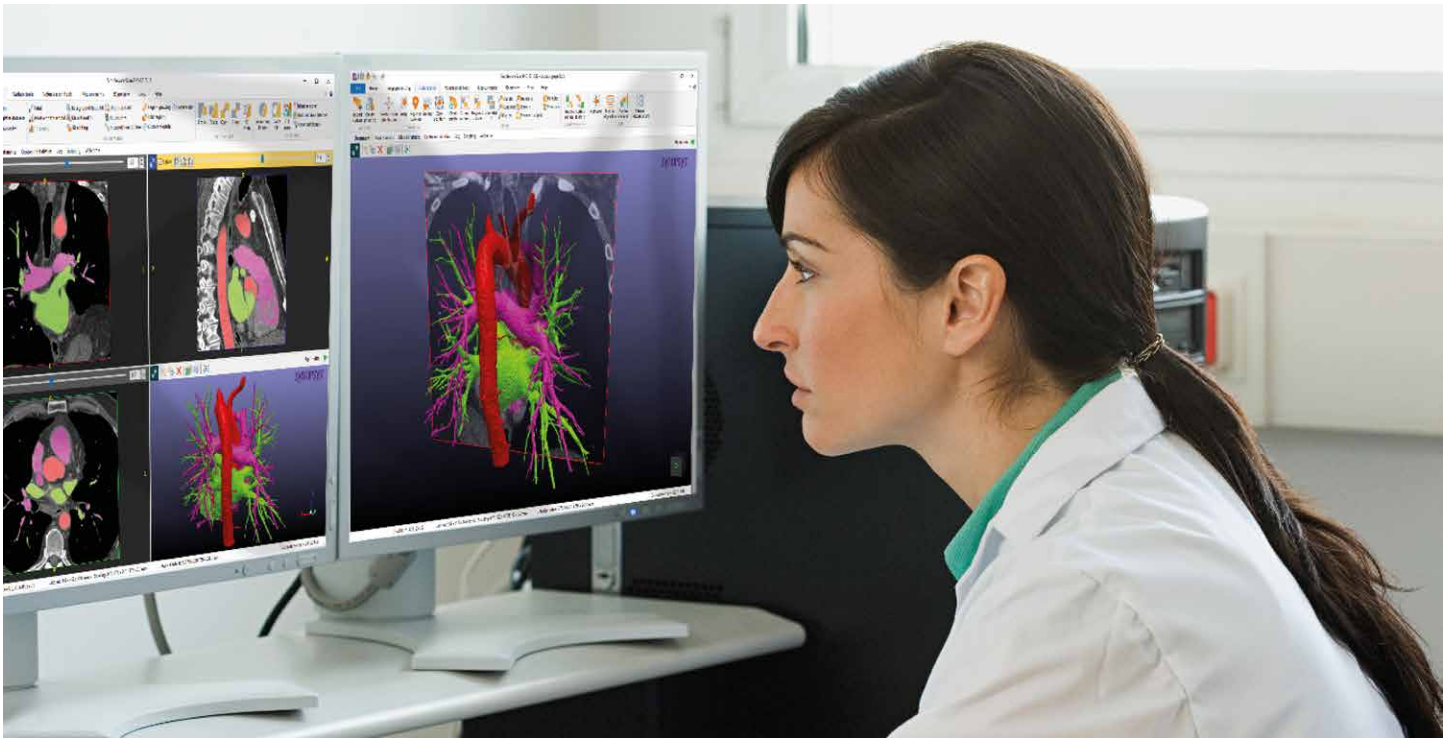

State-of-the-Art Technology

Our industry-leading 3D image processing platform leverages patented technology and enables comprehensive analysis of complex anatomical scans. Increase confidence in clinical decision-making through reliable, repeatable software workflows.

Expert Support and Customization

All licenses come with full support from our team of experts. Our engineers can help you develop your unique and customized workflows, ensuring your use of the software is as efficient as possible, and your final output matches your requirements. Learn how to get the most out of the software with one-to-one sessions, web meetings and tailor-made training courses.

Ease-of-Use

Simpleware Medical provides easy access to all features and functionalities for users who need insights from medical image data. Streamline your medical image processing workflows and export high-quality models to improve confidence in clinical decision-making.

Try Simpleware Medical

Try the software for yourself with a free evaluation version, available on our website. The trial is fully functional and gives you access to the complete Simpleware software suite, a full range of tutorials and technical support.

FDA 510(k) CLEARED

CE 2797

bsi. ISO 13485:2016 Medical Device Quality Management

For more information, go to www.synopsys.com/simpleware

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