SYNOPSYS®

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This document is an electronic copy of the basic 'Instructions for Use' of Simpleware ScanIP Medical Software. Detailed instructions can be found in the 'Reference Guide'.

Simpleware™ ScanIP Medical provides a core image processing interface with additional modules available for Finite Element model generation, CAD integration, NURBS export, and material property calculation. Simpleware ScanIP Medical is the software device, with modules integrating into the same software, rather than representing separate software programs in their own right.

Simpleware ScanIP 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 to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options. Simpleware ScanIP Medical is not intended to be used for mammography imaging.

This product is for professional use only and should be used only by trained technicians with a professional level of English.

English is the language used in the Simpleware ScanIP Medical software interface.

The output must be verified by the responsible clinician.

Simpleware ScanIP Medical has the ability to process, store or discard information contained in medical image files such as DICOM files during the import process of these files. The import process can involve different data transfer methods including USB, CD/DVD, disk drive or server-based storage systems such as PACS. When such files contain personal patient information, it is the responsibility of the end-users to follow the local laws related to appropriate handling of personal data – for example HIPAA (USA) and GDPR (EU) – and to discard any information when required. Please refer to the relevant section in the Reference Guide regarding how personal data is stored and accessible within Simpleware ScanIP Medical, to ensure your usage is compliant.

It is recommended to use Simpleware ScanIP Medical within a hardware and/or network environment in which cyber security controls have been implemented including anti-virus and use of firewall.

Simpleware ScanIP Medical image processing and meshing algorithms are designed to use partial volume effects to improve surface accuracy. The reconstructed 3D surface typically has a maximal error of ½ of a voxel size.

Note: the accuracy of a model is dependent on the image resolution and the quality of the original scan. The accuracy of a model for simulation is also dependent on user requirements and choice of simulation software.

During surface reconstruction, error can be found near sharp edges, which are difficult to reconstruct when using any image-based meshing techniques. Excessive noise in scanned images can also affect surface reconstruction accuracy.

End-users of Simpleware ScanIP Medical can request a free paper copy of this document. To do so, please contact simpleware@synopsys.com.

If information is needed in an emergency, please call +44(0)1392 428750.

In the event that you experience temporary unavailability of this document through the Synopsys website or to the Internet in general, or of your institutional access, we recommend temporarily suspending use of the software until access is restored, unless you have a paper copy of this document.

There are no foreseeable medical emergencies related to this device. If you believe that the device may have directly or indirectly contributed to a patient's injury or death, then please immediately contact simpleware@synopsys.com or call +44(0)1392 428750.

Simpleware ScanIP Medical uses a set of standard symbols (icons) when displaying information dialogs. The table below provides information about the severity of the risk associated with each type of symbol.

Symbol	Meaning