SYNOPSYS®

Simpleware ScanIP
Instructions for Software Use
Version Q-2020.03

Last amended: February 2020 (revision number 1.6).
This document is an electronic copy of the basic 'Instructions for Use' of Simpleware ScanIP Software.
Detailed instructions can be found in the 'Reference Guide'.

Description of Simpleware ScanIP

Simpleware™ ScanIP 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 is the software device, with modules integrating into the same software, rather than representing separate software programs in their own right.

Indications for Use

ScanIP 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. ScanIP is not intended to be used for mammography imaging.

Warnings and Recommendations

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 software interface.

The output must be verified by the responsible clinician.

Simpleware ScanIP 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, to ensure your usage is compliant.

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

Accuracy

Simpleware ScanIP 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.

Other Ways of Viewing this Information and Emergencies

End-users of Simpleware ScanIP 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.

Dialog Symbols

Simpleware ScanIP 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
(i)	• Hint or Information. • Risk level: low. • The provided information may be useful but ignoring it has a very low risk of causing patient injury or death.
(!)	• Warning or potential usage error. • Risk level: medium. • The provided information is related to an operation that has succeeded but the user needs to be aware of details which may indicate undesirable side effects.
(✕)	• Error/operation failure. • Risk level: low. • An operation has failed. Even though the outcome is negative, there is no risk of undesirable side effects.

Instructions for Use

Starting Simpleware ScanIP

After installing the software on your PC, double click the Simpleware ScanIP icon on your desktop. Alternatively, you can click on the Windows icon in the "taskbar" and navigate to **Synopsys > Simpleware ScanIP Q-2020.03**.

The Reference Guide can be opened by clicking on the "Help" button on the Welcome page that appears after starting Simpleware ScanIP.

Simpleware ScanIP usage is controlled through a license key file which may either be node-locked or floating. Instructions for setting up both license options are described in the **Reference Guide**. All required software installers (product and licensing tools) and license keys can be downloaded from **SolvNet (https://solvnet.synopsys.com).** Please note that only active licenses of Simpleware ScanIP will be able to get access to SolvNet.

Supported Operating Systems

- Windows 7*
- Windows 10*†
- Windows Server 2008 R2*
- Windows Server 2016*
- Licensing tools for Linux 32-bit and 64-bit

*Only 64-bit versions of these operating systems are supported.

†Simpleware ScanIP is fully tested on this operating system.

Recommended System Requirements

Operating System	Hardware
• Windows 10 • Windows Server 2016 Only 64-bit operating systems are supported.	• Processor: Intel Core i7 or equivalent • Memory (RAM): 16 GB or higher** • Graphics card: Workstation grade OpenGL 3.2 compatible graphics card with 1024 MB VRAM • Screen resolution: 1920 x 1080; True color (32bit) or more • Disk space: 100 GB ** As a guideline, allow twice as much RAM as your datasets size for volume rendering visualization and about 4 to 8 times for segmentation, surface mesh generation etc. The memory required depends heavily on the size and complexity of your image data and resultant model to be analyzed. Please contact Simpleware Support for further information with any specific queries.

Manufacturer Contact Details

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Simpleware ScanIP is a CE-marked product
UDI Number: (01)00863520000369

Current Availability as a CE-Marked Product

For more information on the current availability and plans for Simpleware ScanIP as a CE-marked product in your country, please contact simpleware@synopsys.com.