SE Suite

Safety User Manual

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Introduction to the Manual

Scope of this Manual

This Safety User Manual contains information for the safe operation of the SE Suite software. It covers the very basics of the application.

Warnings, Cautions and Notes

The following samples show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.

WARNING:
A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION:
A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

Note: Notes provide advice and highlight unusual points. A note is not intended as an instruction.

Disclaimer

Agfa assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

Every care has been taken to ensure the accuracy of the information in this document. However, Agfa assumes no responsibility or liability for errors, inaccuracies or omissions that may appear in this document. To improve reliability, function or design Agfa reserves the right to change the product without further notice. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Caution: In the United States, Federal law restricts medical devices to sale, distribution, and use by or on order of a licensed physician.

Introduction to the SE Suite

This section covers the following topics:

- Overview of SE Suite
- Intended Use
- Intended User
- System Documentation
- Installation
- Training
- Product Complaints
- Compatibility
- Messages
- Patient Data Security
- Compliance
- Safety Directions

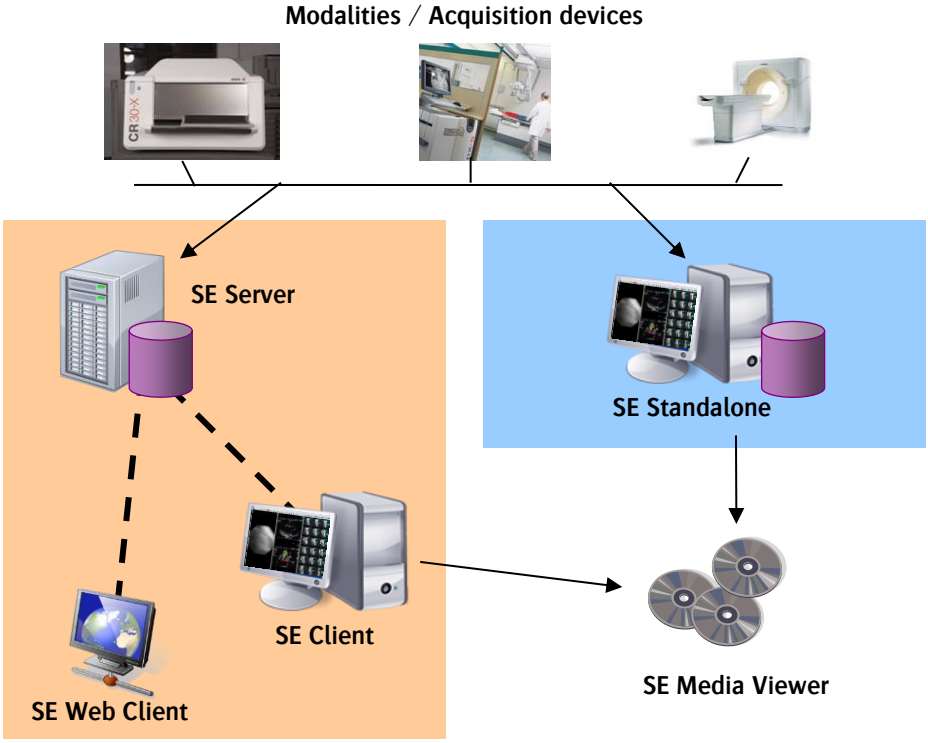
Overview of SE Suite

The SE Suite software is made up of different components which can be installed in different configurations:

- SE Standalone
- SE Server
- SE Client
- SE Web Client
- SE Media Viewer

The configuration will determine the functionality of the SE Suite.

The following diagram illustrates the different components of the SE Suite and shows their place in the different configurations.



Intended Use

The SE Suite software is intended to perform operations relating to the display, digital processing, review, transfer, storage, printing, measurements, and additionally separately cleared third party applications can be integrated. They are intended for use by the physician to aid diagnosis and by medical professionals whenever they require access to medical images and patient demographic information.

Intended User

This manual is written for professional healthcare workers and for users of Agfa products who have received proper training. Users are considered as the persons who actually handle the system as well as the persons having authority over the system.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Before attempting to work with this equipment, the user must thoroughly read and fully understand this manual and any release notes delivered with the software media pack, paying particular attention to all warnings, cautions and notes.

System Documentation

The documentation consists of this Safety User Manual [document 2464] and a Reference User Manual [document 2463] (in English only). The documentation shall be kept with the system for easy reference.

Installation

SE software installation and configuration is to be performed by Agfa or an authorized and trained Agfa dealer.

The integration of this software on properly selected hardware is a critical element when using this software for the purposes described on page 8, and should only performed by Agfa or an authorized Agfa dealer.

A limited number of configuration tasks can also be performed by the customer after a training course has been provided by the authorized Agfa dealer, or by Agfa. Contact your local authorized Agfa dealer for more information.

Training

The user must have received adequate training on the safe and effective use of SE Suite before attempting to work with it. Training requirements may vary from country to country. User must make sure that training is received in accordance with local laws or regulations that have the force of law.

Your local authorized Agfa dealer can provide further information on training. The user must note the following information in the preliminary section of this manual:

☐ “Intended Use” on page 8
☐ “Intended User” on page 8
☐ “Safety Directions” on page 11

Product Complaints

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness, or performance of this product must notify his local authorized Agfa dealer who installed this product, or, ultimately Agfa.

If the device malfunctions and may have caused or contributed to a serious injury of a patient, the local authorized Agfa dealer who installed this product, or, ultimately Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

AgfaService Support - local support addresses and phone numbers are listed on www.agfa.com

Agfa- Septestraat 27, 2640 Mortsel, Belgium
Agfa- Fax +32 3 444 7094

Compatibility

SE Suite software must only be used in combination with other products or components if these are expressly recognized by Agfa as compatible. You should consult Agfa before making changes to the configuration or before adding other software to your system.

Changes or additions to the software must only be carried out by persons authorized to do so by Agfa. Such changes must comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Messages

Under certain conditions the SE software will show a dialog box in the middle of the screen containing a message. This message may tell that either a problem has occurred or that a requested action cannot be performed.
The user must read these messages carefully. It will provide information on what to do from then on. This will be either performing an action to resolve the problem or to contact the local authorized Agfa dealer.

Patient Data Security

The hospital must ensure that the patients' legal requirements are met and that the security of the patient data is guarded.
The hospital must define who can access patient data in which situations.
The hospital must have a strategy available on what to do with patient data in case of a disaster.

Compliance

SE software has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and has been tested as part of the conformity assessment procedures required by 93/42/EEC MDD (European Council Directive 93/42/EEC on Medical Devices).

This Agfa product has been developed to run on hardware compliant with the IEC 60950.

SE software communicates with other devices in the hospital network using one of the following protocols or standards:
☐ DICOM
☐ IHE

Safety Directions

Warning: SE software can only be installed by authorized and trained service personnel. Any hardware configuration running SE software should be selected, configured and setup according to the installation instructions, hardware and software requirements provided by Agfa.

Warning: For use in mission critical environments, redundancy precautions need to be taken with regards to power surges, hardware failure, etc… . At the same time, risks of data loss need to be contained by implementation of suitable backup and data redundancy solutions.

Warning: User access is protected by so-called user profiles. Each user profile is derived from a standard profile (“administrator”, “classic user” or “guest”) and determines to a large extent the users’ options and rights. Modifying the profile settings could prevent users from accessing data and images, functionalities and tools. Caution should be observed when making changes to the user profile settings.

Warning: The SE software can be configured to use more than one database. In this case, the user needs to be aware that only the active database stores any saved preferences, and that only the contents of the active database are queried and shown. The database which is configured as the main database will be opened by default upon program startup.

Warning: The “Image Browser” of the SE software allows the user to filter patient data in the database using different criteria. When a filter is applied, certain patients/studies/series may no longer appear in the displayed list, although they are not deleted from the system.

Warning: The “Image Browser” allows customization of the displayed columns. Newly added columns will always be placed on the far right of the table. By sorting and customizing columns, user could miss relevant information since important columns could be hidden (such as “Study status”).

Warning: Study status should not be used to drive workflow. It is not driven by a RIS, and not automated in any way. It is provided to allow you to share additional status information with other users of the system.

Warning: The SE software allows importing of images from a disk or other medium (on condition that the user has sufficient user rights to perform this operation). This operation may require the user to correctly associate the imported images to the right patient/study/series. Failing to do so, may lead to images being associated to wrong patient names. Manual modifications to the database such as splitting and merging images in different studies (by users with “administrator” rights only) may lead to similar errors.

Warning: Incorrect manipulation can occur during import of elements or any modification within databases (merge/split of patients/studies/series), more precisely at patient/studies/series/image association step. An image could belong to a wrong patient.

Warning: The SE software allows importing of JPEG or TIFF images. The “Measurement calibration” function allows calibrating the geometrical characteristics for this type of images manually. It is user’s responsibility to ensure the correctness of this calibration, since a wrongly calibrated image can lead to wrong measurements on screen and hardcopy.

Warning: In order to prevent data loss, the user must verify any media used for moving data prior to deleting the data from the database.

Warning: When the icon ( ) is displayed on an image in the “Image Display Area”, this indicates that the original orientation/laterality of an image has been altered.

Warning: Once an image is deleted, it may not be recoverable. If you are about to delete an image, SE Suite issues a warning.

Warning: The SE software may be configured to automatically remove the oldest images from the system when a predefined percentage of the available storage capacity is exceeded. It is very important to either ensure sufficient storage capacity for all images, or to acknowledge the possibility that older images will be removed from the system.

Warning: The user is responsible for judging image quality and controlling environmental conditions for diagnostic softcopy or print viewing.

Warning: Many features of the product, including image visualisation, orientation and measurement produce erroneous output if incorrect information is provided by the modalities. Ensure that all users are adequately trained and that the DICOM communication with the modalities is validated prior to using it in a clinical workflow.

Warning: Interpretation of measurement values without a unit (if relevant) might lead to wrong interpretation.

Warning: When using the SE software for diagnostic purposes, the display hardware should be properly selected/setup and calibrated. Users performing mammography examinations must always use grayscale monitors approved for mammography with a minimum of 5 megapixel resolution, or any other hardware in accordance with the local legal requirements.

Warning: To guarantee the complete image quality chain and to be allowed to diagnose with SE Client software, it is mandatory to connect monitor(s) DICOM calibrated and to control regularly the quality of the display according the recommendation of your monitor vendor.

Warning: In case of multi monitor display, different screen calibrations increase the risk of incorrect calibrations which could lead to an undetectable image corruption.

Warning: It is the responsibility of the user to use the SE Client workstation under the same ambient light conditions defined for the calibration of the diagnostic monitor against DICOM grayscale standard display function.

Warning: Images displayed on a monitor may only be considered diagnostic when they are displayed 1) on the correct display hardware (with correct DICOM calibration), 2) from a lossless image format, and 3) when one pixel of the acquired image is represented by one pixel on screen (also known as 1:1 or where the “Pixel size” is 100%). If the “Pixel size” is lower than 100%, the whole image is not properly displayed and information is missing. If the “Pixel size” is greater than 100%, information (pixel data) is created (interpolation) by the system. You can determine the zoom factors by checking the indication displayed at the bottom right of the image, on the top of the window level indication:

Warning: Several SE (Client/Standalone) functionalities rely on screen settings (e.g. measurements, image quality, application rendering…). Therefore, modifying screen settings after software installation and acceptance by a trained service technician becomes the responsibility of the user.

Warning: You must ensure that SE screen settings are properly configured to ensure correct True Size display. Please contact your administrator to adjust screen settings. The screen settings are used to compute the True Size display; wrong settings could lead to wrong measurement results and may jeopardize patient safety.

Warning: An icon (⃠) is displayed in the top left corner of an image if SE detects that the image is lossy compressed. Lossy compressed images are much smaller and enable fast downloads, but are not recommended for diagnosis due to the nature of the compression.

Warning: The magnifier window enabled by the magnifier function can partially hide part of the image and therefore the image could remain not entirely seen.

Warning: SE cannot guarantee that the calibration data received from the modality is accurate. SE cannot guarantee that manual calibrations performed by users were done accurately. No treatment or diagnostic decisions should be based solely on measurements made with the SE software application.

Warning: In the SE software, Modality LUT, VOI LUT and Presentation LUT are always applied on all images by default for all user profiles. The LUT’s can however be undone using the “GSDF toolbar” (which is only accessible by

"administrator" user profiles). Disabling these LUT's (Modality, VOI, Presentation) for an image can result in missing diagnostic information or create undetectable image corruption.

Warning: When cropping an image, certain areas of the original image will be discarded and no longer be displayed, this could lead to omission of clinically relevant data.

Warning: The SE software allows synchronizing 2 slice imaging series manually. When 2 series are synchronized, the following modifications are applied to both of the synchronized series at the same time: panning, zooming (predefined zooms), rotation, flip, zone selection, next image, next page …
Wrongly applied manual synchronization may lead to wrong interpretation of a serie. It is the users' responsibility to ensure proper application of this function.

Warning: The multiplication factor for smart window leveling is defined by your administrator. If the multiplication factor is too high relative to the bit depth of the image, the application will apply excessive window leveling and you may miss important information.

Warning: When using the "DICOM information" option, the displayed information is not updated when selecting another image.

Warning: When using the density pointer tool, the pixel density values are read from the original DICOM data and are not modified by the SE software.

Warning: When using the DICOM query/retrieve function, the user needs to be aware that some servers do not accept queries without search criteria. The user may not be made aware about this when performing this action.

Warning: When using the DICOM query/retrieve function, any studies which are already available in the database, will be replaced with the one which is retrieved from the queried DICOM source.

Warning: When using the query/retrieve priors function, the date range must be greater than the time interval between two screening exposures, to make sure that existing priors will be available and displayed.

Warning: You must ensure that your printer is properly configured to ensure that you receive the expected printing results. Please contact your administrator to adjust printer settings.

Warning: Image printing on non-DICOM desktop printers is not intended for diagnosis purposes.

Warning: When printing mammography images, it is important to note that you may only print one image per film, the print must be scaled to 100%, and all images within a study must be printed. Mammography hardcopies only provide diagnostic quality when printed on devices approved for mammography printing.

Warning: When information overlay is hidden, relevant measurements or recommendations (annotations) on images could be missed.

Warning: If Imager Pixel Spacing data is not present in the DICOM header of a mammography image, the application will not provide measurement information. Measurements are possible, but the measurements will be returned in # of pixels.

Warning: There is no guaranteed level of uncertainty for measurements made with the application and the precision of measurement results does not imply a particular uncertainty as uncertainty is influenced by a number of factors, many beyond the control of the product. The uncertainty of measurements is limited by at least three factors:

1. The quality of the input data, including the uncertainty of the scanner calibration,
2. User's ability to select appropriate points on the screen,
3. The transformations inherent in generating images on a finite pixel display.

It is the user's responsibility to understand these limitations and to use the measurement tools responsibly. No treatment or diagnostic decisions should be based solely on measurements made with the application. If no measurement calibration has been performed, measurement unit is pixel.

Warning: By missing the "stack mode" icon  , images of a series could remain unseen.

Warning: Disabling 'Display DICOM information on the side opposite the member" option will increase the risk of obscuring views of breast tissue with DICOM information.

Warning: SE supports only the markers from iCAD and R2. CAD-systems

Warning: CAD markers are by definition only an aid for diagnosis. Final diagnosis should be performed on original images without CAD.

Caution: SE Standalone supports the following CAD markers:

- CAD markers from iCAD (Masses: ellipse, Micro calcification: rectangle)
- CAD markers from R2 (Masses: triangle, Micro calcification: asterisks)

Warning: If an image is not in the spatial plane defined by the orientation information, SE will not automatically orient the image when using Hanging Protocols. For example, SE will not re-orientation an image from Patient Orientation ('P/L') to Patient Orientation ('P/FL').

Warning: If the "additional exposures" option is not enabled, it is possible that not all images will be viewed, and important diagnostic information missed.

Warning: When merging patients and their respective stored reports in Word format, the patient data in the Word reports will not be updated.

Warning: The SE software supports MPR (multi planar reconstruction) and MIP (maximum intensity projection) as additional tools to two-dimensional medical imaging display techniques. These reconstruction algorithms involve interpolation of data. Reconstructed images should not be used as the only basis for a diagnosis.

Caution: Inadequate system and network setup can cause data access delays. Follow the SE Suite hardware requirements, software requirements and network settings guidelines closely. Solution must be installed by authorized service engineer.

Caution: We do not advise turning off all patient demographics in the image area. Configuring the SE Client so no patient demographics are immediately visible in the image area, introduces a risk of misidentifying a patient.

Caution: Any user with an "administrator" profile can enable a feature in the software allowing the simultaneous display of series from different patients. Using this option is risky because it could lead to possible confusion between image series of different patients. (This option is disabled by default, and should be used with great caution).

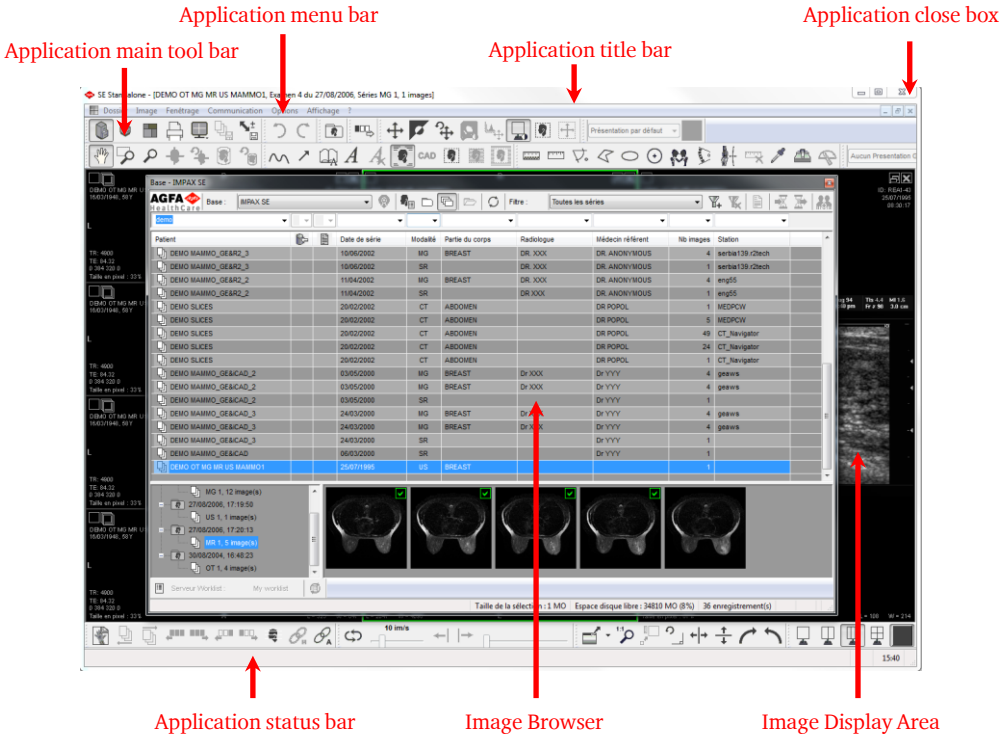
Getting Started

Starting SE

1. Double-click the **SE Client** (or SE Standalone) shortcut.
   Or, select **Start** > **Programs** > **Agfa** > **SE Client (or SE Standalone)**.
2. When the SE login is displayed, type your **User ID** and **Password**.

Note: The password is case sensitive. If you cannot login, check whether Caps Lock is enabled on your keyboard.

3. Click **OK**.
4. After successful login, you get the **Main Application Window** below.



Find images to view

1. Select context to view image information.

	Patient context
	Study context
	Series context

2. In the **Image Browser** list, ensure that **SE** is selected as the database.
3. Filter the list of data by selecting or typing relevant text in the list box above each column in the Image Browser.
   Or, select a filter from the **Filter** list in the **Image Browser**.

Display images

1. While in Study or Series context, double-click a study or series in the **Image Browser** list view.

	Study context
	Series context

2. Double-click a study or series in the tree view.
3. Double-click an image or series in the thumbnail view.

Common keyboard shortcuts: Image Browser

To	Press
Switch between the Image browser and Image Area	F2
Refresh the list of studies, images of series	F5
Mark an image thumbnail	Enter
Select all image thumbnails	CTRL – A
Deselect thumbnail selection	CTRL – D

Common keyboard shortcuts: Navigation

To	Press
Display the previous series of a patient within the same study	-
Display the next series of a patient within the same study	+
Display the first image of a series	Home
Display the last image of a series	End
Navigate backward to the previous page of images	Page Up
Navigate forward to the next page of images	Page Down
Navigate to the previous image	Up Arrow
Navigate to the next image	Down Arrow

Common Keyboard Shortcuts: Image Area

To	Press
Switch between the Image browser and Image Area	F2
Configure a print layout	F4
Mark an image	Enter
Send marked images to a print layout	F7
Apply optimal window level	0
Apply saved window level presets 1 through 9	1 - 9
Invert window level settings	/
Revert to the default window level settings	*
Reset zoom, pan, window level and orientation	R
Undo the most recent change	CTRL – Z
Redo the most recent change	CTRL – Y
Start or stop cine mode from the first frame	Space
Navigate to the next open series	Tab
Select all images in a series	CTRL – A
Deselect selection	CTRL – D
Close the active series	SHIFT – F4
Close all series	CTRL – F4

Top Image Area Tools

Button	Name	Use
	List	Switch between the Image Browser and Image area
	Series Tray	Toggle the series tray
	Print Layout	Toggle the print layout dialog
	Pan	Move images around on screen
	Dynamic Zoom	Magnify or reduce images dynamically
	Arrow	Place an arrow to point to areas of interest
	Text Annotation	Add freeform markup text to an image
	Distance Measurement	Measure the distance between two points
	Window Level	Manual window leveling adjustment
	Invert	Exchange white and black areas in an image.
	MPR	Perform MPR on selected series
	MIP	Perform MIP on selected series

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