

Intended use. Visage Ease Pro is a mobile client for diagnostic image viewing of radiological images from the following modalities: X-ray, CT, MRI, PET, SPECT, Ultrasound and XA. It is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images within and outside health care environments.

Visage Ease Pro must only be used by trained health care professionals. It may support physicians and/or the medical staff by providing mobile access to relevant medical images. Any diagnostic or therapeutic decision resides with the doctors and/or the medical staff in their respective area of responsibility.

Visage Ease Pro is not intended to replace full radiologic reading workstations. It must not be used in the context of diagnostic or therapeutic decisions if a radiologic reading workstation with appropriate display hardware is available. The user must make sure that the reading environment complies with any applicable diagnostic requirements and the state-of-the-art.

Visage Ease Pro must not be used for primary image diagnosis in mammography or digital breast tomosynthesis.

Hardware requirements. Visage Ease Pro is intended to be used with Apple's mobile iOS devices. For diagnostic image review, Visage Ease Pro should be used on an iPad 3 or iPad Air running iOS 12.0 or higher.

Viewing conditions. Recommended viewing conditions for diagnostic image viewing are in a dimly lit office environment (with less than 100 lux), away from overhead fluorescent lights and exterior windows. This is an environment similar to a radiology reading room.

Safety guidelines. To ensure a safe and effective use of the device the following guidelines have to be taken into account. The given measures must be performed before Visage Ease Pro is started.

Ambient light affects the contrast of the device. Bad environment lighting conditions, e.g. direct sunlight or unsuitable room lighting, might result in an insufficient contrast for image interpretation. Before rendering a diagnostic or therapeutic decision, the Ambient Lighting test should be performed to ensure acceptable conditions.

Display brightness should be set to maximum intensity and the Auto-Brightness feature should be disabled to ensure proper luminance of the displayed images. The Ambient Lighting test helps to notice if the brightness is too low.

Foreign matter on the screen may obscure the image data and reduce contrast. The device's touch screen should be wiped before and during use if necessary, e.g. with a lens cloth, to avoid smudges, fingerprints, and artifacts.

Reduced image quality might decrease the display of subtle image details. A red bullet in the upper right corner indicates reduced image quality, e.g. by lossy compression.

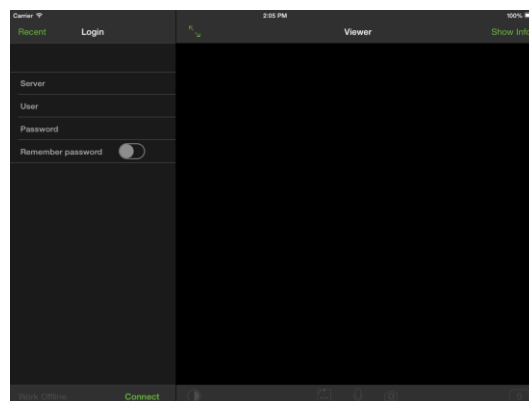
Mobile access to the image data is affected by the wireless signal strength whether using Wi-Fi or a cellular network. Download time depends on the network speed, for example a 100 slice CT can range from 15 seconds (Wi-Fi), to 4 minutes (3G), to 20+ minutes (Edge).

Display backlight and wireless communication might reduce battery life significantly. It is important to maintain the charge of the device or have a power supply within easy access.

Getting Started – Visage Ease Pro

Connecting.

Start Visage Ease Pro and enter the address of the Visage 7 Server, username and password. Use the same user credentials as for logging in with the Visage 7 Client. If you do not know the login details, please contact your system administrator. Tap “Connect” to connect to the Visage 7 Server. Enable Touch ID or Face ID for convenient and secure future logins. If you switch on “Remember password”, Visage Ease Pro remembers your password for future logins. Consider using the Passcode lock or similar methods compliant with your local IT policies to prevent unauthorized access to your mobile device.



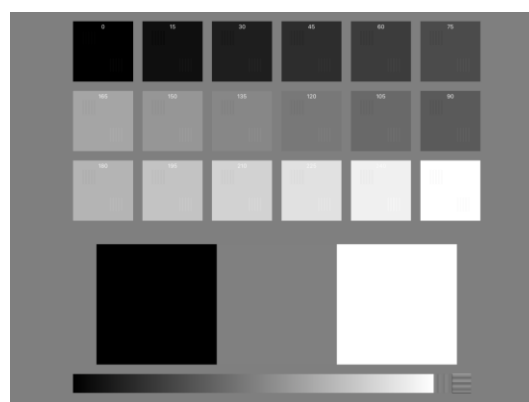
Verifying ambient lighting.

After logging in, Visage Ease Pro presents a grey screen containing a low-contrast area at a random position. If you can locate and tap the grey square, then the ambient lighting in your environment is acceptable. If you fail three times (the grey square is repositioned after each try), the current environment is not suitable for diagnostic image viewing. A dialog with hints on improving the lighting conditions will be displayed and all images are shown with a red banner stating “Not for diagnostic use”. You may repeat the Verify Lighting test at any time from the Info dialog or by tapping the red banner.



Assessing display quality.

From the Info dialog, select “Display Quality Assessment”. Go through the eight test patterns and confirm or decline if the display quality in the current environment allows for discernment of the requisite details in the provided patterns. If you decline, you are asked to find an environment with better lighting conditions before rendering a diagnostic or therapeutic decision.



Getting Started – Visage Ease Pro

Navigating.

If the displayed series contains multiple images, pan up or down to browse through the image stack. If zoomed in or the W/L mode is active, pan up or down on the left or right viewer border for browsing. Alternatively, open the image slider by tapping the bottom right framed number to navigate the image stack. Press and hold one of the arrow buttons to scroll continuously through the images of the series. When scrolling starts and you release the arrow button, the cine mode locks for continuous playing. You may adjust the cine speed in the Settings section of your device.



Swipe left or right to switch to the next or previous series of the displayed study if available.

Double tap the image viewer to bring it to temporary full screen, double tap it again to restore the previous viewer layout.

Use the layout buttons on top of the viewing area to change the current viewer layout, drag & drop series to load from the Patient Jacket into the desired viewer or select a series to be opened in the active viewer.

Multi planar reformats (MPR).*)

Using the MPR tool (cube icon), a volumetric data set can be reformatted by setting the viewing direction, e.g. anterior-posterior or head-foot, the slice thickness and the projection mode (Average IP, Maximum IP, and Minimum IP). The image orientation is indicated by orientation labels in the center of the viewer borders.



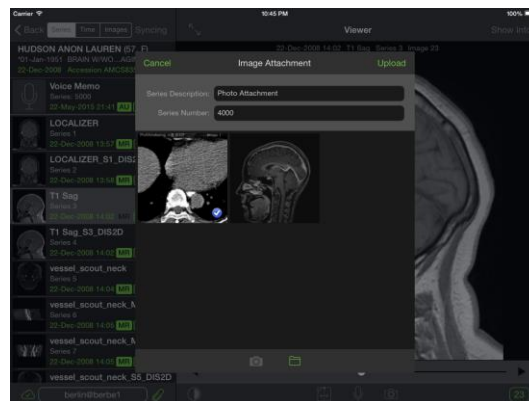
Screenshots. *)

Tap the screenshot button to take a picture of the image viewer's content. The screenshot is automatically stored in your regular photo album. Use the Photo App for viewing or emailing your screenshots.

Getting Started – Visage Ease Pro

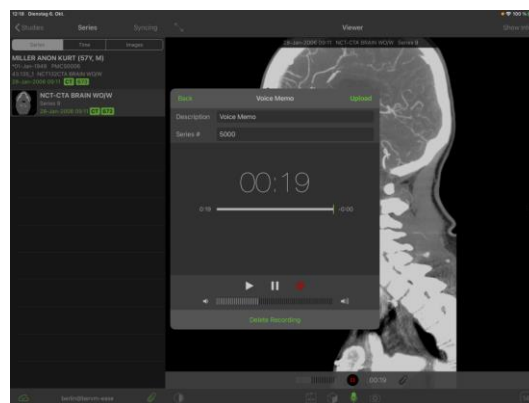
Uploading images and videos.*)

Attach photos, images, or videos to a selected study or patient by tapping on the attachment icon in the lower tool bar of the series view. For each upload, a new series is created and added to the respective study or patient. The Image Attachment dialog allows you to select a study description (for attachments to a patient) and to edit the series description and the series number. Choose between images or videos already taken (folder icon) or use the camera to take new pictures or videos (camera icon). Select/deselect images and videos in the Image Attachment dialog with a simple tap. Only selected images and videos indicated by a blue checkmark will be uploaded. Double tapping an image shows it in full screen.



Recording voice memos.*)

Attach voice memos to a selected study by tapping the microphone icon in the image viewer's tool bar. This expands the basic recording controls. Tap the record button to start recording. The recording duration is shown in red and the record icon changes to a button that opens the voice memo view. In this view, your recording is paused and you may change the description and series number of the new series that will be added to the respective study. With the buttons of the lower tool bar you choose to continue with your recording (record icon), to pause the recording again (pause icon) or to listen to a playback of your recording (play icon). During recording a level meter and position slider is shown. In playback mode, a slider to change the system volume is shown instead of the level meter. After recording you can either discard or upload your voice memo. The back button closes the voice memo view while recording is continued. During recording it is possible to switch to another series of the same study. If you switch back to the study list with an unfinished recording, an alert view will be shown.



*) Available if the appropriate user level permissions are set.

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This software is CE-compliant and is defined as a class IIa medical device in accordance with Medical Devices Directive 93/42/EEC.

All product and company names are trademarks or registered trademarks of the respective companies.

Some of the specifications described herein may not be currently available in all countries. Please contact your local sales representative for the most current information.

Information in this manual may be subject to changes without prior announcement.

Caution

US federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).



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Symbols to Convey Information Essential for Proper Use



Manufacturer



CE-mark with reference number of VI's Notified Body (TÜV Rheinland LGA Products GmbH)