

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 9.0 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 have to 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.

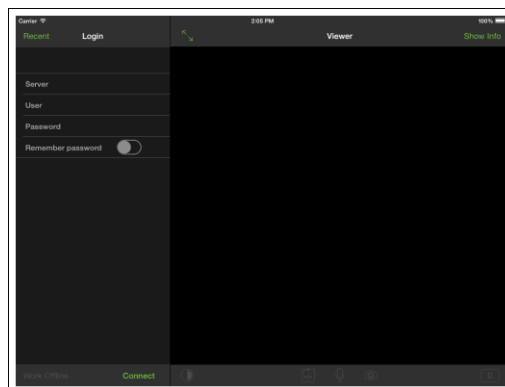
Mobile access to the image data is affected by the wireless signal strength whether using Wi-Fi or a cellular network. Download time depends on the network speed, for example a 100 slice CT can range from 15 seconds (Wi-Fi), to 4 minutes (3G), to 20+ minutes (Edge).

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, user name 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.



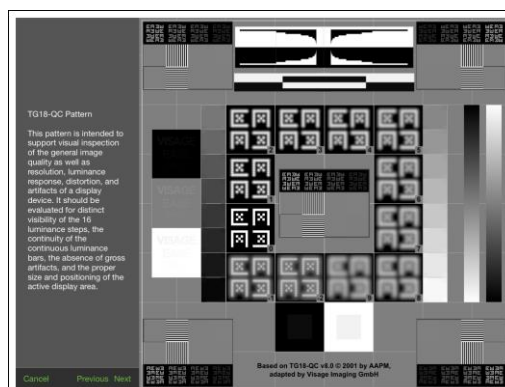
Verifying ambient lighting.

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.

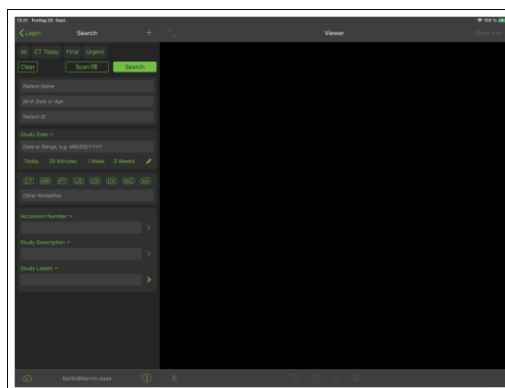
From the Info dialog, select “AAPM-TG18 test patterns...”. Go through the four test patterns and confirm or decline if the display quality in the current environment allows for discernment of the requisite details in the provided patterns. If you decline, you are asked to find an environment with better lighting conditions before rendering a diagnostic or therapeutic decision.



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Searching.

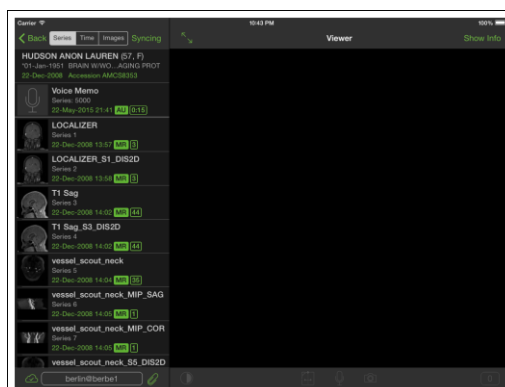
The Search view allows searching for studies on the Visage 7 server. Enter search criteria like patient name, study date, modality, or accession number and tap the Search button, or use one of your Visage 7 search presets shown at the top to find all matching studies. You can also create and save search presets with the '+' button. Do a long press on a search preset to update, rename, or delete it. Alternatively, scan a bar or QR code to find a specific patient or study.*)



The list of studies can be sorted by patient name (default) or study date by tapping the respective button in the navigation bar. A section index [A...Z] allows you to navigate easily through the patient names. By tapping a letter, the list automatically shows the corresponding studies. Choose one of the listed studies and Visage Ease Pro shows the series of the selected study. Here, you may sort the series list by series number (default), acquisition time, or number of images by using the buttons in the navigation bar. The list entries are grouped by type, i.e. reports, voice memos, and image series.

Viewing.

Select one series for viewing from the series list. Visage Ease Pro displays the first image of the selected series and some minimal series information as overlaid text. Tap "Show Info" to display further patient and study information. The image viewer allows you to interact with the image in different modes that you can select from the toolbar. The default mode is Pan/Zoom for moving and resizing the image. Use one finger to pan and two fingers to zoom the image. Double tap in the middle of the viewer to reset the image display. Select the Window/Level mode for adjusting image brightness and contrast manually. Move your finger up/down to increase/decrease image brightness or left/right to increase/decrease image contrast. Double tap in the middle of the viewer to reset the window level settings. Alternatively, choose one of the presets from the Window/Level menu. In the Rotate/Flip mode, you may rotate by 90° to the left/right, flip horizontally/vertically or reset the image orientation.



Select the Window/Level mode for adjusting image brightness and contrast manually. Move your finger up/down to increase/decrease image brightness or left/right to increase/decrease image contrast. Double tap in the middle of the viewer to reset the window level settings. Alternatively, choose one of the presets from the Window/Level menu. In the Rotate/Flip mode, you may rotate by 90° to the left/right, flip horizontally/vertically or reset the image orientation.

Navigating.

Select the Browse/Cine mode if the currently displayed series contains multiple images. Browse through the image stack by dragging the slider or tapping an arrow button. Press and hold on one of these 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. Double tap on the left/right border of the image viewer to jump to the previous/next series if available.



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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. If “Show Info” is tapped, an additional length scale is displayed.

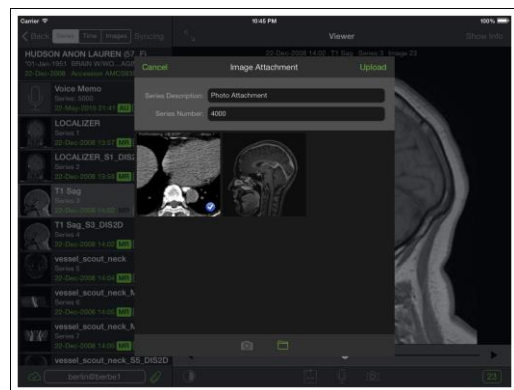


Screenshots. *)

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.

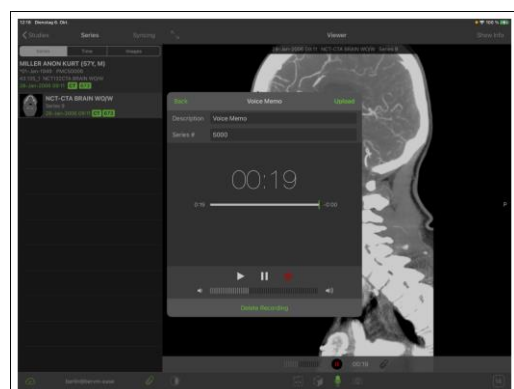
Uploading images and videos. *)

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.



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Caching images.

Images displayed by Visage Ease Pro are automatically cached on the mobile device to prevent accessing the same image multiple times on the Visage 7 Server. You may additionally cache specific studies or series in advance, e.g. to prepare a ward round or conference where you might need to display the images without network connection. Select the “Syncing” button in the navigation bar of the Studies or Series screen to enter the local cache’s update mode. Tap a study/series to add it to the cache (indicated by the insertion symbol “+”) or to remove it from the cache (indicated by the deletion symbol “-”). If the caching of a study/series is currently in progress, you may stop it by tapping the item until neither the insertion nor the deletion symbol is shown. Choose “Update” to trigger the selected caching actions or “Cancel” to leave the update mode without changing the cache. Tap the cache status button in the lower left corner to get information on the current cache status. On the Cache Status screen you may cancel currently queued downloads or clear the whole cache by tapping the lower left or lower right button, respectively.



*) 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)