



USER'S MANUAL
Volk Pictor
Digital Imaging Device

The system component options are:

Pictor digital imager with optics lenses and accessories:

Component:	Description:	Accessories
Retina Module (VP1RET)	module for eye fundus imaging	silicone eye piece
Anterior Module (VP1ANT)	module for exterior ophthalmic imaging	-----
Dermatoscopic module (VP1DERM)	module for dermatoscopic imaging	-----
Otoscopic module (VP1OTO)	module for otoscopic imaging	ear specula pack air pump
Imaging handset (VP1HAND)	handset for general imaging	
Cradle (VPCRADLE)	for data transmission and battery charging	USB cord Power unit

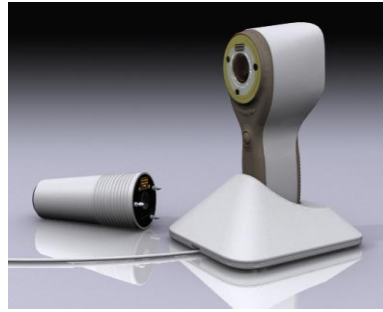
The following accessory can be purchased separately:

- **Pictor Slit Lamp Adapter (VPSLM)** that enables the camera to be used as stationary imaging tool.

Quick start guide

WHAT TO DO BEFORE THE FIRST USE:

1. Remove Pictor from the packaging and check that all parts are undamaged.
2. Install Battery as instructed in the **Appendix B, end of this manual**.
3. Place Cradle on a desk next to the computer.
4. Connect the other end of the USB-cable to the computer.
5. Connect power unit to the wall plug (mains)
6. Place Pictor handset in the cradle. Battery starts to charge. Charge battery for four hours before the first use. When device is not used, it may be stored in the Cradle.



Guideline for device storage:

If battery is stored out of the camera for longer period of time, battery shall be charged every 9 months.

If battery is stored in the camera, camera shall be placed in the cradle with cradle power cable connected.

Normal battery life time is expected to be 1-2 years.

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Appendixes:

Appendix A: Electromagnetic compatibility information

Appendix B: Battery replacement

1. Indications for use

Pictor is a medical digital camera that is used with dedicated optics modules intended to take images of the eye fundus, surface of the eye, ear canal and tympanic membrane, and skin.

Image and video data is intended for documentation and consultation.

Supported optics modules and their intended uses are:

Component:	Description:
VP1RET	module for fundus imaging
VP1ANT	module for exterior ophthalmic imaging
VP1DERM	module for dermatoscopic imaging
VP1OTO	module for otoscopic imaging
VP1HAND	handset for general imaging

2. Contraindications for use of the posterior segment module VP1RET

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed necessary illumination to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

3. Warnings and cautions

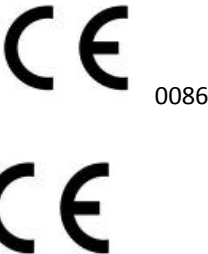






Use only accessories and battery provided by Volk with this product.



Place computer and cradle outside the patient environment (at least 4 feet distance from the patient).

4. Important symbols

Symbol	Description
	<p>The CE mark on this product indicates it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive. CE mark with notified body identification number indicates a class IIa product.</p>
	<p>Read accompanying user documentation indicates that important operating instructions are included in this User's and Maintenance Manual. Failure to follow these instructions could place the patient or operator at risk.</p>
	<p>Type BF applied parts.</p> <p>Applied part is a part of Pictor that in normal use necessarily comes into physical contact with the patient.</p>
 <p>9V, 1.1 A</p>	<p>Charger polarity symbol, voltage and power</p>
	<p>Sticker at the front of the device indicating integrated general imaging optics focal length and F-number.</p>



5. Parts of the device



Cradle:





Soft key indicators:

Position	Indicator	Purpose
Left soft key		To power on the device To power off the device, with long press
Right soft key		Open menu with long press

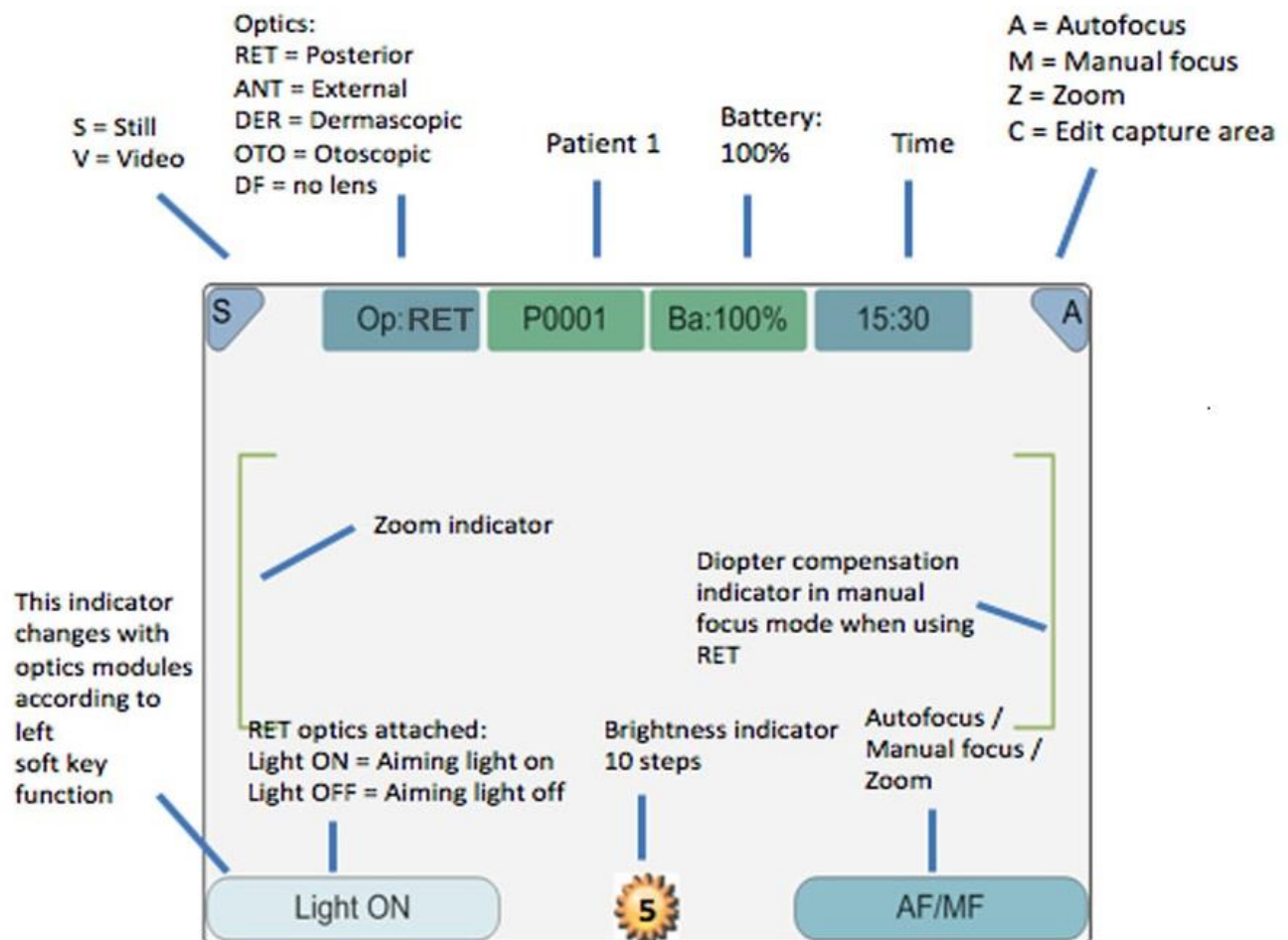
LED indicators:

The recharging and connection to the computer is indicated with green (charging) and blue (connection) LED-lights:

Position	Indicator	Purpose
Left LED-indicator Green		Active when device is powered on
Right LED-indicator Blue		Active when devices is placed to the cradle and connected to a computer

Graphical indicators:

These indicators are displayed on the top row of the display during imaging:



6. Usage environment requirements

Pictor is designed for use in a medical environment.



CAUTION:

Pictor is not suitable for use in the presence of flammable anaesthetics.

Pictor is intended to be use inside in a normal room temperature and normal humidity. Do not use Pictor in an environment where there is possibility that water condenses to or inside Pictor. The type of power source is indicated in Chapter 15, Technical description.



CAUTION:

It is only allowed to attach USB cable and Power source provided into the cradle, If you need replacement to the USB cable or Power source please contact Volk.

USB Cable must be connected only to the USB port of a computer that complies with the IEC 60950 standard. Avoid using excessive power or twisting the connector when connecting the USB cord to a computer.

Place computer and cradle outside the patient environment (at least 4 feet distance from the patient).

To transfer patient image data the device must be used together with a computer. The device does not need any drivers to be installed on a computer.

Device can be used with all major patient database application supporting both textual and image data recording.

The device must be used according to this manual, quick reference guide and / or information found on the Volk.com website.

Electromagnetic compatibility information and recommended separation distances between portable and mobile RF communications equipment and Pictor are given in the Appendix A.

7. Operating instructions

This chapter gives instructions for using the device. More specific instructions for using modules are given in the modules' chapters.

7.1. Preparations

Pictor is both charged and connected to a computer using the provided cradle. When Pictor is not use, it may be stored in the cradle. Storing device in the cradle is not harmful for the battery, because the battery is charged only when the charge drops below a certain limit.

To connect Pictor to the cradle gently connect it to the connector hole. The device can be connected to the cradle with module attached.

7.2. Connection to a Computer

Image data transfer method to a computer is similar as in a digital camera.

When connected to a computer, it is possible to simply open the folder to view and then store files to the hard disk of the computer.

7.3. Basic use – starting up, shutting down and taking an image

Device is powered on by pressing left soft key.

It is possible to capture both still images and video. Image capture mode is changed from camera menu that opens by pressing right soft key for 1s.

Still image is captured using the dual action shutter to the second position. Video is captured by keeping the dual action shutter pressed down in the second position.

Taken image will stay on display until it is cleared by pressing right or left soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.

To transfer images to a computer, place device to the cradle. The image transfer and charging is indicated with green and blue LED-lights and text on LCD-screen.

Pictor verifies if image data is erased when:

- Device is powered on from power off mode or power save mode
- Device is removed from the cradle

It is recommended that image data storage is always erased with a new patient.

Device is powered off by keeping left soft key pressed down over 1 second.



CAUTION:

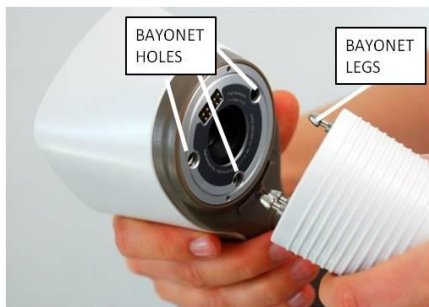
When device is powered on, powered off or goes to standby mode the handset issues noise. This noise is normal and is not a sign of any damage or problem.

7.4. Attaching and detaching optics module



CAUTION:

Imaging modules used with Pictor must include text 'Pictor'. It is not allowed to attach other objects to the bayonet connector.



Module is attached by placing it in front of the bayonet area of the device. Three bayonet legs are placed in the holes and the module is pressed firmly into the handset



Module is released by sliding release button that is located in front of the device above the dual action shutter.

7.5. Device Menu

Menu is opened by pressing a right soft key  for 1s.

Menu has six tabs. One is for device settings such as language selection. There is one tab for retinal imaging (RET), anterior eye imaging (ANT), ear imaging (OTO), skin imaging (DER) and general imaging (DF).

Arrow keys are used to move between tabs: use arrow key up until tab is active and use left and right arrow keys to change active tab. Light blue color indicates active tab.

Arrow keys change values in the menu. Active value is indicated with light blue color. Changed values are saved by using left soft key (“OK”) and cancelled by pressing right soft key (“Cancel”). Some values are confirmed by pressing the Middle key.



Table below includes explanations of the Device settings tab:

Setting	Values (default bolded)	Purpose
Preview images	Ok	To preview the images on camera press Ok.
New patient folder	Ok	To create a new patient folder press Ok. New patient folder can also be created in live view by long pressing the middle key.
Erase image memory	Ok	Select Ok to erase images and videos from camera SD card.
Display brightness	Low-Med- High	Use left and right arrow keys to adjust display brightness
Icons	On/Off	Show graphical icons when imaging.
Sounds	On/Off	When enabled, sound is played during image capture
Keyboard backlight	On/Off	When enabled, keyboard illumination is on
Select language	ENG - FRA-GER-ITA-JPN-POR-SPA	Use left and right arrow keys to select camera language
USB write protection	On/Off	When enabled, writing to SD card is not allowed when device is in cradle. This feature helps prevent any viruses getting from the computer to the camera.
Video file format	MPEG4 /MPEG1	Use left and right arrow keys to select video file format
Image transfer method	UMS /WIA	Use WIA for automatic and UMS for end-user activated image transfer. UMS can be used in most cases.
Restore factory Setting	Ok	To restore all settings menus to factory defaults. Activate using the middle key
Date	DD-MM-YYYY	Use left and right arrow keys to set date. Use Middle key to select next field
Time	HH:MM	Use left and right arrow keys to set time. Use Middle key to select next field
Camera SW version	Show camera SW version	Browse version information with left and right arrow key
Start query	Era ./Fol./None	Choose the startup query between memory erase, new patient folder or no query at all.
Set Data Cable Type	CRA /SLI	Feature Not yet Available
Remote Trigger	On/Off	Feature Not yet Available

Preview images

Image preview is opened by selecting “Preview files” with a middle key. Images are browsed by using arrow keys. Display gives information about usage of the image preview.

Image can be zoomed while previewing by pressing middle key. Move around the image by pressing arrow keys. Change between the four zoom levels by pressing middle key.

Resolution of the image preview is rather small. Preview is intended only for the quick check that all necessary information is captured and for showing pathologies for the patient. It is recommended always to study full resolution pictures on a computer screen.

New Patient Folder

A new patient folder is created by pressing middle key when the New patient folder selection is active in Device menu. A new patient folder can also be created by pressing Middle key for 3 seconds when in live view. If the current patient folder is empty a new folder cannot be created.

Erase Image Memory

Image memory can be erased by selecting “Erase Image Memory” in Device menu. This selection is activated by pressing middle key. The camera also prompts the question “Erase image memory?” when camera is powered on or removed from cradle.

Display brightness

The Display brightness selection has three options: low, medium and high. Choose the suitable level of display brightness according to for example how the examination room is lit up.

Icons

The icons shown on camera screen can be enabled or disabled to the user’s liking. The most essential icons such as Menu icon are always visible.

Sounds

By default the camera makes a sound during image capture. This sound can be turned off from Device menu.

Keyboard backlight

By default the camera keys have a backlight lit up when the camera is turned on. This light can be turned off from Device menu if it disturbs the user while taking images.

Language

The camera has six different languages the user can choose from. Default language is English and the language selection is always shown in English in menu.

USB write protection

USB write protection is recommended to be turned on by user. When protection is on this feature will prevent any virus from entering the camera from a computer when connected to the cradle.

Video file format

The camera has two file formats that user can choose for videos: MPEG4 and MPEG1. MPEG4 is a higher quality file format but may not be viewed with all video players. MPEG1 format is more widely supported by different SW applications.

Image transfer method

There are two options for the image transfer method: UMS (USB Mass Storage) or WIA (Windows Image Acquisition).

Restore factory settings

By selecting “Activate” in Device menu and pressing middle key, “Restore factory defaults” selection the original factory settings will be returned.

Date

Date can be set using the left and right arrow keys. Enable editing by using the Middle key. Move between day, month and year by pressing the middle key.

Time

Time can be set using the left and right arrow keys. Enable editing by using the Middle key. Move between hours and minutes by pressing the middle key.

Camera SW version

This item in Device menu tells the camera SW version.

Start query

User can choose start-up query between erasing images, creating new patient folder or no query at all. When erasing images is chosen as the query the camera will prompt user on start-up whether all images and videos shall be deleted. When new patient folder query is chosen the camera will ask if a new patient folder shall be created upon start-up to prevent from mixing images with previous patient. If no query is selected then camera will go directly to live view upon start-up.

7.6. Adjusting focus and automatic focus

The camera has an autofocus function where camera finds correct focus place automatically. Automatic focusing start when shutter is pressed half way down (icon at the top right corner of the display shows icon “A”). The focus mode (Auto / Manual) can be changed by pressing right soft key.

Image focus can be adjusted manually by pressing arrow keys up and down. When focus mode is set to manual and VP1RET module is attached a dioptre scale is visible on the screen.

7.7. Patient Information Editor

What Is Patient Information Entry?

The Pictor Plus has a feature that allows entry and editing of patient information (e.g., patient name, ID number or other identifier information).

- The patient information can contain a maximum of 32 characters, including letters (upper or lower case), numbers and some special characters: () , . : - _ @ / and space.
- Which patient eye being imaged – left or right – can also be set.
- Additionally, the type of image saved (IR illuminated, normal color, red-free or color corrected) is also saved automatically.
 - IR illuminated = IR
 - Normal color = Co
 - Red-free = RF
 - Color corrected = CC

Where Is The Patient Information Saved?

The patient information is saved as part of the jpeg image file in two different locations:

- Location 1: the Exif data field (Exif = exchangeable image file format)
 - The Exif data field is embedded inside the jpeg image file. It can be accessed using typical EMR software that is set up to read the Exif field or by using Exif viewing software (e.g., Exif Pilot).
 - For example, if “John Doe 123” were entered for the patient information, then the Exif field would contain:
Patient ID:John Doe 123
 - If the Left setting were selected for John Doe, then the Exif field would also contain:
Side:Left
 - If the particular image for John Doe were a color corrected image, then the Exif field would also contain:
Image type:CC
 - The entire Exif data field would be:
Patient ID:John Doe 123,Side:Left,Image type:CC
- Location 2: the jpeg filename
 - The jpeg filename has 8 characters with a “.jpg” extension.
 - The first 3 characters of the jpeg filename are reserved for the first 3 characters of the patient information. If the Patient Information is shorter than 3 characters, the remaining characters are defaulted to underscore marks: _
 - The last character of the jpeg filename is reserved for the type of image:
 - IR illuminated = I
 - Normal color = N
 - Red-free = R
 - Color corrected = C
 - The middle 4 characters are reserved as a counter for the number of images taken: 0000 to 9999, then rolling over to 0000 again.
 - For example, if “John Doe 123” were entered for the patient information as per the above example, then the jpeg filename would be:
JOHxxxxC.JPG

How Is Patient Information Entered?

Patient information is entered in the Patient Information screen. The Patient Information screen allows setting of which eye will be imaged (left or right). It also allows access to the Patient Information editing screen.

The current Patient Information entered will be displayed to the right of the Patient ID icon. The default value is "ABC12345."

- Selecting patient side: left or right
 - In the Patient Information entry screen, use the arrow keys to navigate to the Patient Side icon.
 - Select the Patient Side icon using the middle key.
 - Use the left or right arrow keys OR the middle key to toggle between the Left or Right side icons.
 - Use the up or down arrow keys to navigate out of the Patient Side setting, which saves your selection.
- Editing the Patient Information
 - Use the up and down arrows to navigate to the Patient ID icon, and select it using the middle key.
 - This will open the Patient Information editor screen.
 - The Patient Information editor screen includes a simple, on-screen keyboard in ABC-123 order, as well as the special characters mentioned above. It also includes a white editing field at the top of the screen.
 - The 4 arrow keys are used to navigate to the desired character or up to the white editing field.
 - The middle key is used to select that character, which will then appear at the top of the Patient Information editor screen in the editing field.
 - Toggle between upper or lower case characters by using the left soft key below the A/a icon.
 - Exit the editor screen by using the right soft key below the Exit icon. This saves the entered Patient Information.
 - To delete a character:
 - Arrow up to the white editor field at the top of the screen.
 - Use the left or right arrow keys to navigate the blinking cursor to the position AT THE IMMEDIATE RIGHT of the character you want to delete.
 - Press the middle button to delete the character.

In the Patient Information screen:

- Use the left soft key under the OK icon to save the Patient Information settings and exit the Patient Information screen, OR
- Use the right soft key under the Cancel icon to discard any changes and exit the Patient Information screen.

How To Access The Patient Information Screen

When powering on the Pictor Plus:

- When the Pictor Plus starts up after being powered on or being removed from its charging cradle, it automatically presents an option to "Edit current patient information?" in the startup screen.
 - Select Yes (left soft button) to proceed to the Patient Information entry screen.
 - Select No (right soft button) to proceed to the live view screen.
- This will set the Patient Information for the next images taken.

When in the camera live view screen, using the Menu button (right soft key, long press):

- Use the right soft key (long press) to access the Menu screen
- Under the Device tab, the Patient Information entry screen can be accessed from either the Preview images icon or the New patient folder icon.
- From the Preview images icon, you can use the Patient Information entry screen to edit Patient Information on images *you have already taken*.
 - You can edit Patient Information for ALL of the images in a selected folder, OR
 - You can edit Patient Information for a single, selected image file.
- Arrow to the Preview images icon and select with the middle key to access the Image Browser screen.
- In the Image Browser screen, use the arrow keys to navigate to a specific folder or a specific image file.
 - When only a folder is selected, the folder name will be highlighted with white text (the filenames will be dark).
 - When an image file is selected, that filename AND its folder name will be highlighted with white text.
- When your selected folder or image file is highlighted, press the right soft key under the Edit icon to access the Patient Information entry screen and edit the Patient Information per the above instructions.

REMEMBER:

IF YOU ARE EDITING PATIENT INFORMATION FOR A FOLDER, **ALL** OF THE IMAGE FILES IN THAT FOLDER WILL BE CHANGED TO THE NEW PATIENT INFORMATION.


IF YOU ARE EDITING A SINGLE IMAGE FILE, ONLY THAT IMAGE FILE WILL BE CHANGED TO THE NEW PATIENT INFORMATION

- From the New patient folder icon, you can use the Patient Information entry screen to set Patient Information for images that you are going to take next.
 - Arrow to the New patient folder icon and select with the middle key.
 - The device will prompt “Create a new patient folder for new patient images?”
 - Select Yes (left soft key) if you also wish to create a new patient folder in which to save your next images.
 - Select No (right soft key) if you do not want a new patient folder.
 - Next, the device will prompt “Edit current patient information?”
 - Select Yes (left soft key) to enter the Patient Information entry screen.
 - Proceed to edit Patient Information per the above instructions.
 - Your next images will have the new Patient Information.
 - Select No (right soft key) to return to the Device tab without editing Patient Information.

7.8. Reset button

Reset button can be used if device behavior is abnormal (this should not happen too often).



Reset button is located in a small opening under display. Button is marked with circle .

Reset button can be pressed with a thin object such as a paper clip. Button needs to be pressed for over 7 seconds.



8. Eye Fundus imaging using module VP1RET

Pictor VP1RET is intended to capture digital images and video of the fundus of the human eye. The device set for ophthalmic imaging consists of:

- Camera handset VP1HAND
- Attachable ophthalmic module VP1RET
- Silicone support for VP1RET
- Cradle for charging and image transfer

VP1RET is intended for non-mydriatic imaging. This means that infrared is used for targeting image to the eye fundus and visible light is flashed when image is taken. Pupil does not respond to the infrared light so examination is convenient for the patient. Constant illumination can be selected from device menu if mydriatic drops are used. Pictures can also be taken using infrared light for both aiming and capturing.

STEPS FOR FUNDUS IMAGING:

1. The examination room should be as dark as possible.
2. Both the patient and the examiner shall be seated while taking the images. Patient is asked to look at a target on a wall 6-9 feet behind the operator (patient's eye targets to infinity and stays still).
3. Either autofocus or manual focus can be used. Autofocus range is -11 to +3 diopters, manual focus range is -20 to +20 diopters.

If patient has a refractive error and **autofocus is off**, focus need to be adjusted:

- Hyperopia: camera is focused to distance by pressing arrow key up. One click of the key is approximately 2 Dioptres.
- Myopia: camera is focused closer by pressing arrow key down. One click of the key is approximately 2 Dioptres.

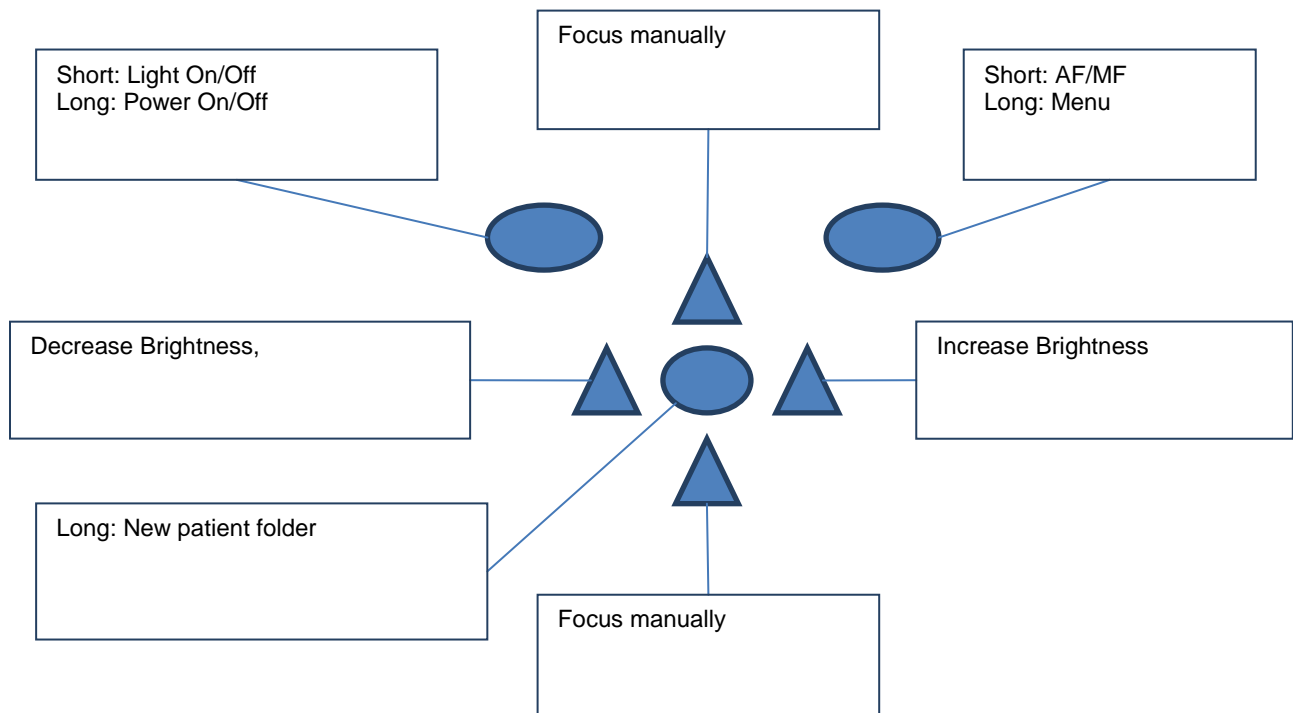
4. **Ophthalmoscope aiming light is turned on** by pressing the shutter key (in front of the device) half way down or by pressing the left soft key.
5. Light is adjusted using left and right arrow key. There are altogether 10 brightness levels. Default value is 5. Suitable illumination is typically 2 to 8. Infrared used for targeting can be adjusted from menu. Usually there is no need to adjust infrared.
6. Approaching the eye is started from 4 inches (10 centimeters) distance. **Patient is asked to look at a target on a wall 6-9 feet (2-3 meters) behind the operator (patient's eye targets to infinity and stays still).** Pupil is approached until the reflection from the eye fundus can be seen. The right imaging distance is about 0.8 inch (2 cm). Silicone support must be compressed approximately half way down.

Camera is stabilised by keeping the outer side of the hand against the patient's forehead. Example of the correct usage position is shown below:



7. Still image is captured by pressing the shutter key all the way down. Video is captured by keeping shutter down. Taken image is displayed on screen until user clears the image by pressing shutter, left or right soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.
8. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
9. Transfer images to a computer after capturing images. Images are transferred to the computer when camera is placed to the cradle. VP1HAND works as any other digital camera.
10. When camera is removed from the cradle it verifies image data storage erase. It is recommended that image data storage is always erased before images are captured of a new patient.

The camera keys function as shown in image below when VP1RET optics module is attached:



Below table provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Light On / Off	The aiming light can be turned on and off by pressing Left soft key. The aiming light (IR or white) can also be turned on by half pressing the shutter button.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus	Switch between Auto and Manual focus by pressing Right soft key. Autofocus range is -11 to +3 diopters, manual focus range is -20 to +20 diopters.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-----	Change brightness	Use left and right arrow keys to adjust capture light brightness. Aiming light brightness is adjusted in menu.
Up/Down arrow	-----	Focus manually	When manual focus is active use up and down arrow keys to focus. Press arrow key up when patient has myopia. Press arrow key down when patient has hyperopia.

Table below includes explanations of the RET settings tab for retinal imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Shoot mode	Normal / Auto	In Auto mode camera takes picture automatically after focusing. In Normal mode user must press shutter button to second position to take picture after focusing.
Mark side	On/ Off	Mark side of the eye to the image data.
IR brightness	Low- Med -High	Use left and right arrow keys to set infrared brightness for VP1RET eye fundus lens.
Red-free	On /Off	Saves a copy of an eye image using green color channel only. Can be used with VP1RET optics
Save IR image	On/ Off	Saves an image taken with IR light in addition to white light image when turned on.
Illumination mode	IR/White , IR/IR, White/White	Use left and right arrow keys to select aiming and capture light source.
Aim help	On /Off	When enabled the camera indicates with a red/green rectangle if aim on the retina is good enough for image capturing. When Auto is chosen the camera takes image automatically once rectangle turns green (aim on retina is good).

Capture mode

Both still images and video can be taken with the Pictor VP1HAND camera. When taking video the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Shoot mode

Shoot mode function can be used when autofocus is enabled. There are two shoot modes to choose from: normal and auto.

In normal mode the camera will focus when shutter button is pressed half way down and take a picture when shutter button is pressed all the way down.

In auto mode when shutter button is pressed the camera will focus and take a picture automatically.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. When On side is marked to the file name and to the image. For video files, side is always marked only to the file name.

When marking side is enabled, camera verifies side after each captured image.

Identifiers used for eye images are OS for left and OD for right.

IR brightness

Infrared illumination brightness has three levels: low, medium and high.

Red-free

If red-free image is enabled from menu, then camera will save a picture using only green channel at the same time when saving original picture.

Camera stores selected menu settings when it is powered off.

Save IR image

If Save IR image is enabled from menu the camera will save an image taken with IR image in addition to saving a color image taken with white light.

Illumination mode

Illumination mode can be set to IR/White, IR/IR or White/White. In IR/White mode aiming is done using infrared light and image is captured using white light. The pupil does not react to infrared light and thus it is recommended to use IR/White mode whenever possible. In IR/IR mode both aiming and image capture are done with infrared light. In White/White mode aiming and image capture are done with white light.

Aim help

Aim help feature indicates to user when the aim on retina is good for taking an image. If the rectangle is red the aim is not good and retina does not fully cover the image area. If the rectangle is green the aim is good and image can be taken.

9. Eye imaging using external ophthalmic module VP1ANT

Volk Pictor VP1ANT is intended to capture images and video of the surface of the human eye and surrounding areas. The device set for external ophthalmic imaging consists of:

- Camera handset VP1HAND
- Attachable external ophthalmic lens VP1ANT
- Cradle for charging and image transfer

VP1ANT optics module has two light sources, white and cobalt blue light. User can choose between the light sources by pressing left soft key when VP1ANT module is attached. Cobalt blue light enables taking fluorescent pictures of the surface of the eye to reveal any cuts or defects.

STEPS FOR EYE SURFACE IMAGING:

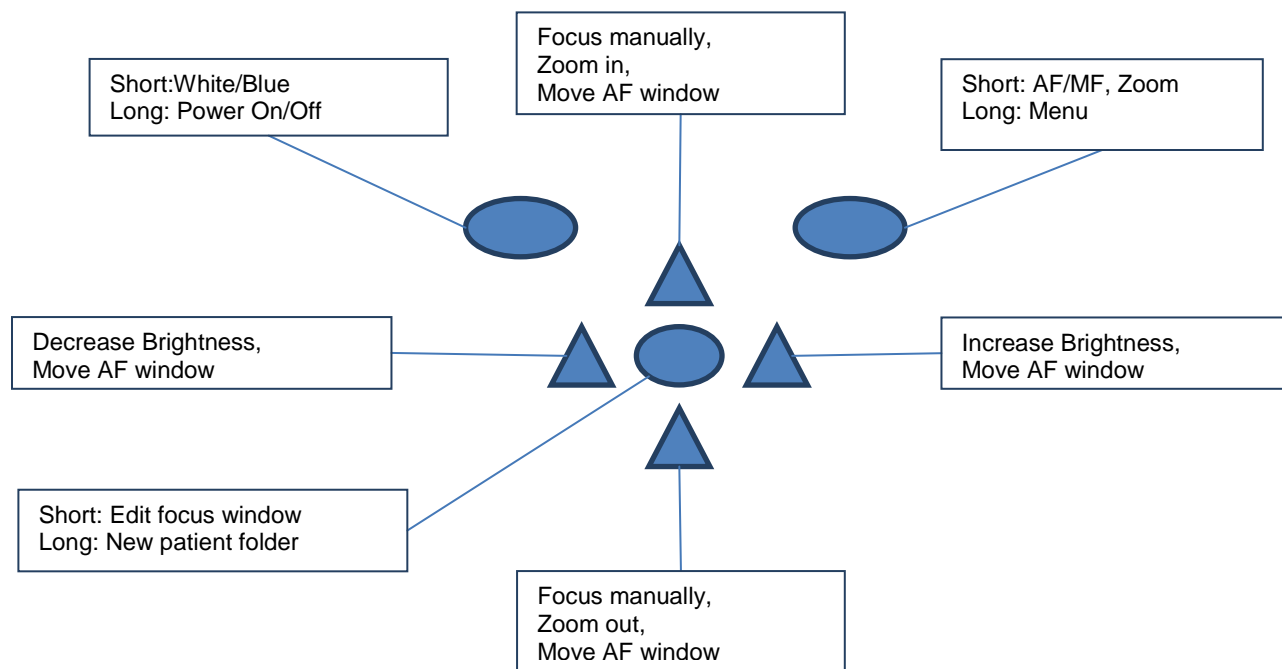
1. After VP1ANT optics module is attached the light source is chosen by pressing left soft key.
2. Still or video image is selected. Selection is made in ANT menu.
3. **It is recommended to use autofocus.**
4. **Ophthalmic aiming light is turned on** by pressing the shutter key (in front of the device) half way down.
5. Light is adjusted using left and right arrow key. There are altogether 10 brightness levels. Default value is 5. Suitable illumination is typically 2 to 8.
6. Place the optics module cup on patient's eye. Patient can be asked to look at different directions depending on what area of the eye needs to be captured.

Camera is stabilised by keeping the outer side of the hand against the patient's forehead. Example of the correct usage position is shown below:



7. Still image is captured by pressing the shutter key all the way down. Video is captured by keeping shutter down. Taken image is displayed on screen until user clears the image by pressing shutter, left or right soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.
8. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
9. Transfer images to a computer after capturing images. Images are transferred to the computer when camera is placed to the cradle. VP1HAND works as any other digital camera.
10. When camera is removed from the cradle it verifies image data storage erase. It is recommended that image data storage is always erased before images are captured of a new patient.

The camera keys function as shown in image below when VP1ANT optics module is attached:



Below table provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	White / Blue	Choose between white and blue illumination by pressing left soft key. Blue light can be used with fluorescent applied on the eye to reveal any cuts or defects.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus	Switch between Auto and Manual focus by pressing Right soft key.
	Short	Activate Zoom	Press Right soft key to activate zoom function. Digital zoom can be used for close up of features and image focus. Icon “Z” displayed in up right corner of display when active. Zoom value is saved to camera memory.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Short	Edit focus window	When focus window is visible it is possible to move it using arrow keys to better capture the wanted area.
	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient’s images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Aiming light brightness is adjusted in menu.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. The Window returns to original position when camera is put to cradle, turned off or optics module detached.
Up/Down arrow	-	Focus manually	Use up and down arrows to focus manually.
	-	Zoom In / Out	Zoom in using arrow key up. Zoom out using arrow key down. There are four zoom levels: 1,2,4 and 6. Zoom value is saved to camera memory.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate.

Table below includes explanations of the ANT settings tab for anterior eye imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Focus window	Visible /Hidden	Use left and right arrow keys to choose between having focus window visible or hidden.
Shoot mode	Normal / Auto	In Auto mode camera takes picture automatically after focusing. In Normal mode user must press shutter button to second position to take picture after focusing.
Mark side	On/Off	Mark side of the eye to the image data.
Zoom cropping	On/Off	When turned on camera will save the zoomed area only. When turned off camera will save the whole image area even when zoom is used.

Capture mode

Both still images and video can be taken with the Pictor VP1HAND camera. When taking video the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Focus Window

Focus Window help user position the image. The Focus Window can be moved on the screen by first pressing Middle key until icon “F” appears in up right corner of display and then using the arrow keys when aiming.

Shoot mode

Shoot mode function can be used when autofocus is enabled. There are two shoot modes to choose from: normal and auto.

In normal mode the camera will focus when shutter button is pressed half way down and take a picture when shutter button is pressed all the way down.

In auto mode when shutter button is pressed the camera will focus and take a picture automatically.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. When On side is marked to the file name and to the image. For video files, side is always marked only to the file name.

When marking side is enabled, camera verifies side after each captured image. Identifiers used for eye images are OS for left and OD for right.

Zoom cropping

With zoom cropping on the camera will save the zoomed area instead of the whole image area. When zoom cropping is turned off then camera will save the whole image area instead of the area that is visible on the camera screen when user has zoomed in.

Camera stores selected menu settings when it is powered off.

10. Ear imaging using otoscopic lens Pictor VP1HAND/VP1OTO

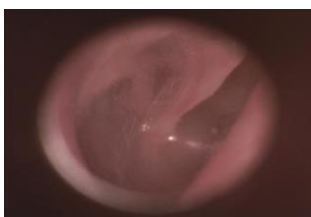
Volk Pictor VP1HAND VP1OTO digital otoscope is intended to capture digital images and video of the ear canal and tympanic membrane. The device set for otoscopic imaging consists of:

- Camera handset VP1HAND
- Attachable otoscopic lens VP1OTO
- Otoscopic specula (type “beta-Heine”)
- (air pump)

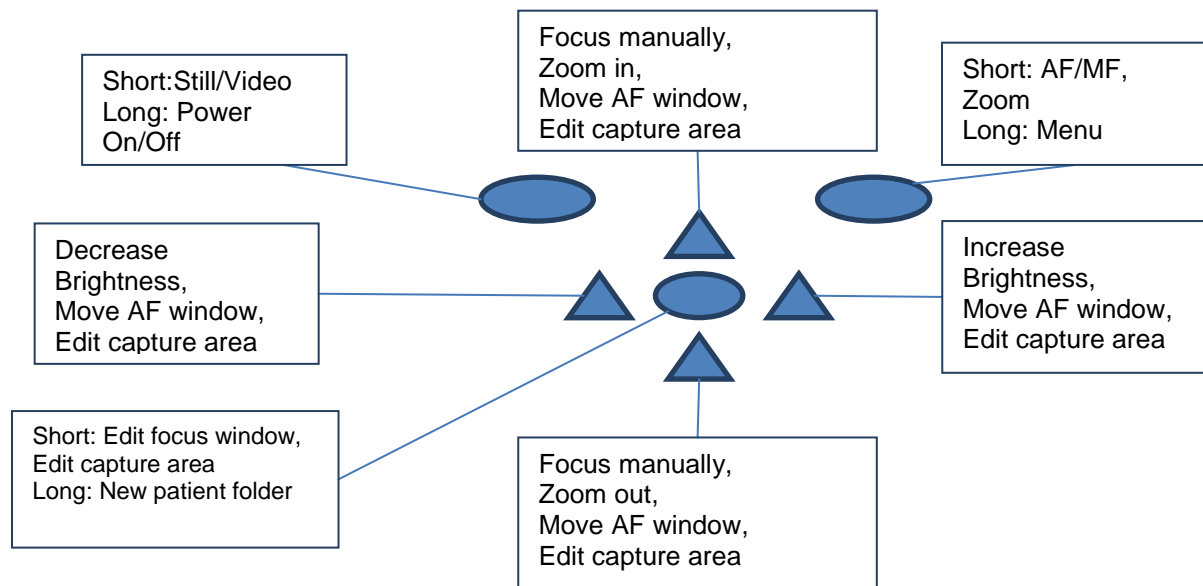
Otoscope can be used with widely available type “beta-Heine/allspec” speculas.

Steps for capturing ear images are:

1. Attach otoscopic lens. Press firmly until you hear a clicking sound to make sure module connects properly.
2. Attach specula.
3. Start illumination by pressing shutter half way down. Adjust illumination by using left and right arrow keys.
4. Adjust focus if needed by pressing arrow keys up and down. **It is recommended to use autofocus.** Automatic focusing starts when shutter is pressed half way down (top right corner of the display shows icon “A”). If pressing shutter does not activate automatic focusing, autofocus needs to be activated from right soft key.
5. Use digital zoom for close up of features if needed: press right soft key to activate Zoom (upper right corner shows “Z”) and arrow key up or down to adjust zoom. There are four zoom levels: 1, 2, 4 and 6. Press right soft key to re-activate focus if needed.
6. Due to slight differences between individual specula the image area may not be completely visible or tilted to the side when using zoom. Press Middle key to access “Edit capture area” function. Then you can move the image area to the center of the screen.
7. Capture image by pressing shutter button all the way down. Still image is captured by pressing the shutter key all the way down. Video is captured by keeping shutter down. Taken image is displayed on screen until user clears the image by pressing shutter, left or right soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.
8. If multiple patients are examined during one session, create a new file folder for each patient by pressing middle key for over 3 seconds.
9. When imaging is ready, store images on a computer: Place camera to the cradle and image transfer starts. VP1HAND works as any other digital camera connected to a computer.



The camera keys function as shown in image below when VP1OTO optics module is attached:



Below table provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Still / Video	Choose between still image and video shooting by pressing left soft key.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus	Switch between Auto and Manual focus by pressing Right soft key.
	Short	Activate Zoom	Press Right soft key to activate zoom function. Digital zoom can be used for close up of features and image focus. Icon "Z" displayed in up right corner of display when active.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Short	Edit focus window	When focus window is visible it is possible to move it using arrow keys to better capture the wanted area.
	Short	Edit capture area	Due to differences between specula the image area can be tilted to the side of the screen when using small specula. Press Middle key to enter "Edit capture area" function and move image area to center of the screen.
	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Aiming light brightness is adjusted in menu.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. The Window returns to original position when camera is put to cradle, turned off or optics module detached.
	-	Edit capture area	Use left and right arrow keys to adjust capture area to center of screen after activating with Middle key.
Up/Down arrow	-	Focus manually	Use up and down arrows to focus manually.
	-	Zoom In / Out	Zoom in using arrow key up. Zoom out using arrow key down. There are four zoom levels: 1,2,4 and 6. Zoom value is saved to camera memory.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate.
	-	Edit capture area	Use up and down arrow keys to adjust capture area to center of screen after activating with Middle key.

Table below includes explanations of the OT settings tab for ear imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Focus window	Visible /Hidden	Use left and right arrow keys to choose between having focus window visible or hidden.
Shoot mode	Normal / Auto	In Auto mode camera takes picture automatically after focusing. In Normal mode user must press shutter button to second position to take picture after focusing.
Mark side	On/ Off	Mark side of the ear to the image data.
Zoom cropping	On /Off	When turned on camera will save the zoomed area only. When turned off camera will save the whole image area even when zoom is used.

Capture mode

Both still images and video can be taken with the Pictor VP1HAND camera. Capture mode can be chosen in OTO menu and when using VP1OTO otoscopic module from left soft key. When taking video the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Focus Window

Focus Window help user position the image. The Focus Window can be moved on the screen by first pressing Middle key until icon “F” appears in up right corner of display and then using the arrow keys when aiming.

Shoot mode

Shoot mode function can be used when autofocus is enabled. There are two shoot modes to choose from: normal and auto.

In normal mode the camera will focus when shutter button is pressed half way down and take a picture when shutter button is pressed all the way down.

In auto mode when shutter button is pressed the camera will focus and take a picture automatically.

Marking side

It is possible to mark which ear was imaged. Marking side is enabled from the menu. When On side is marked to the file name and to the image. For video files, side is always marked only to the file name.

When marking side is enabled, camera verifies side after each captured image.

Identifiers used for ear images are Left/LE and Right/RI.

Zoom cropping

With zoom cropping on the camera will save the zoomed area instead of the whole image area. When zoom cropping is turned off then camera will save the whole image area instead of the area that is visible on the camera screen when user has zoomed in.

Camera stores selected menu settings when it is powered off.

11. Skin Imaging using dermatoscopic optics module VP1HAND and VP1DERM

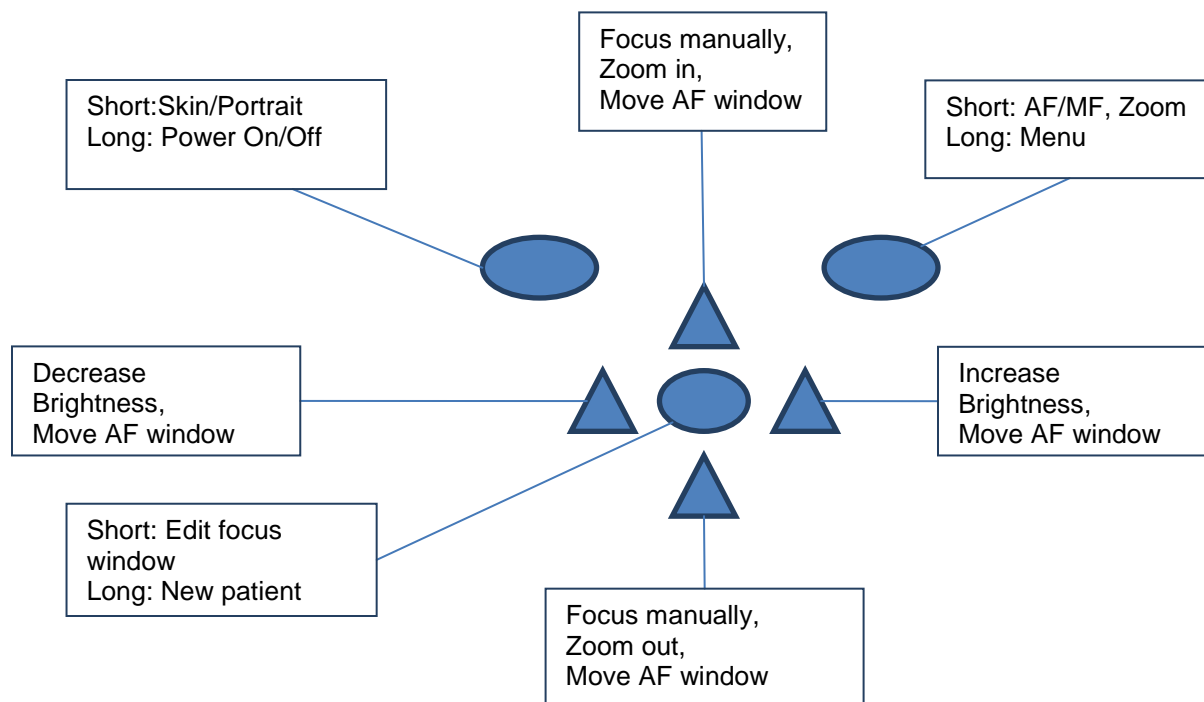
With attachable skin optics module VP1DERM camera can be used for storing digital images and video of the skin.

Steps for capturing skin images are:

1. Attach skin optics module. Press firmly until you hear a clicking sound to make module connect properly.
2. Press module gently to the skin. You may use immersion fluids such as aqueous disinfectant.
3. **Adjust illumination** by using left and right arrow keys.
4. **Adjust focus** if needed by pressing arrow keys up and down. It is recommended to use autofocus. Automatic focusing starts when shutter is pressed half way down. If pressing shutter does not activate automatic focusing, autofocus needs to be activated from right soft key.
5. Use digital zoom for close up of features if needed: press right soft key to activate Zoom (upper right corner shows "Z") and arrow key up or down to adjust zoom. There are four zoom levels: 1, 2, 4 and 6. Press right soft key to re-activate focus if needed. Zoom value is saved to camera memory.
6. Activate portrait mode by pressing left soft key when taking an image of a larger area such as head, whole arm or the whole body. The icon on the bottom left corner of screen now says "Portrait" instead of "Skin".
7. Capture image by pressing shutter button all the way down. Still image is captured by pressing the shutter key all the way down. Video is captured by keeping shutter down. Taken image is displayed on screen until user clears the image by pressing shutter, left or right soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.
8. If multiple patients are examined during one session, create a new file folder for each patient by pressing middle key for over 3 seconds.
9. After taking pictures, store images on a computer: Place camera to the cradle and image transfer starts. VP1HAND works as any other digital camera connected to a computer.



The camera keys function as shown in image below when VP1DERM optics module is attached:



Below table provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Skin / Portrait	Press left soft key to switch between Skin and Portrait modes. When taking an image of the skin close up use Skin mode. When taking an image of larger area use Portrait mode.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus	Switch between Auto and Manual focus by pressing Right soft key.
	Short	Activate Zoom	Press Right soft key to activate zoom function. Digital zoom can be used for close up of features and image focus. Icon “Z” displayed in up right corner of display when active.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Short	Edit focus window	When focus window is visible it is possible to move it using arrow keys to better capture the wanted area.
	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient’s images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Aiming light brightness is adjusted in menu.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. The Window returns to original position when camera is put to cradle, turned off or optics module detached.
Up/Down arrow	-	Focus manually	Use up and down arrows to focus manually.
	-	Zoom In / Out	Zoom in using arrow key up. Zoom out using arrow key down. There are four zoom levels: 1,2,4 and 6.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. Zoom value is saved to camera memory.

Table below includes explanations of the DER settings tab for skin imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Focus window	Visible /Hidden	Use left and right arrow keys to choose between having focus window visible or hidden.
Shoot mode	Normal / Auto	In Auto mode camera takes picture automatically after focusing. In Normal mode user must press shutter button to second position to take picture after focusing.
Skin body map	On/Off	Mark body part to image and image name.
Skin / Portrait	Skin /Portrait	Select skin when taking close-up pictures of skin. Select Portrait when taking portrait pictures.
Zoom cropping	On/Off	When turned on camera will save the zoomed area only. When turned off camera will save the whole image area even when zoom is used.

Capture mode

Both still images and video can be taken with the Pictor VP1HAND camera. Capture mode can be chosen in OTO menu and when using VP1OTO otoscopic module from left soft key. When taking video the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Focus Window

Focus Window help user position the image. The Focus Window can be moved on the screen by first pressing Middle key until icon “F” appears in up right corner of display and then using the arrow keys when aiming.

Shoot mode

Shoot mode function can be used when autofocus is enabled. There are two shoot modes to choose from: normal and auto.

In normal mode the camera will focus when shutter button is pressed half way down and take a picture when shutter button is pressed all the way down.

In auto mode when shutter button is pressed the camera will focus and take a picture automatically.

Skin body map

Skin body mapping can be used when taking dermatoscopic images to mark on the image and image name the body part which was imaged. Camera will display options of body parts after an image is captured. Choose the correct body part by using arrow keys and soft keys.

Skin / Portrait

This feature allows taking images from close up and from further away with the skin module. To take a close-up image choose “Skin” mode (this is on by default). To take an image of larger area such as the head choose “Portrait”.

Zoom cropping

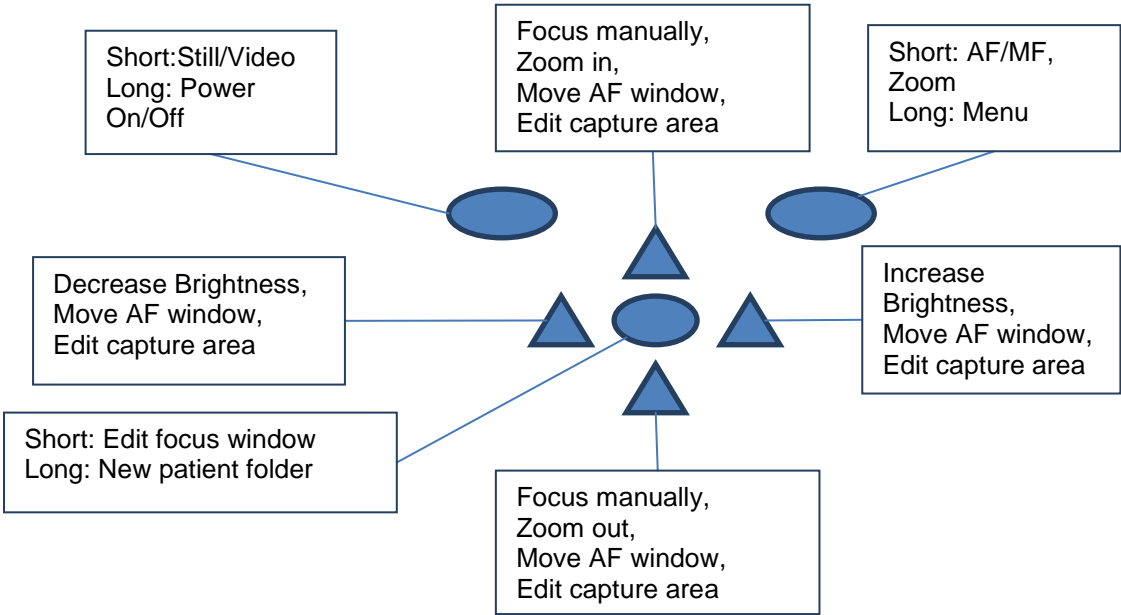
With zoom cropping on the camera will save the zoomed area instead of the whole image area. When zoom cropping is turned off then camera will save the whole image area instead of the area that is visible on the camera screen when user has zoomed in.

Camera stores selected menu settings when it is powered off.

12. General imaging without optics module

It is possible to take pictures using Pictor VP1HAND without any optics module. When taking images without additional optics, integration time that corresponds to the brightness of the image is adjusted using left and right arrow key. Indicator for integration time is shown at the bottom of the display.

Below picture shows the functions of camera keys when no optics is attached.



Key	Press	Function	Explanation
Left soft key	Short	Still / Video	Choose between still image and video shooting by pressing left soft key.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Auto / Manual focus	Switch between Auto and Manual focus by pressing Right soft key.
	Short	Activate Zoom	Press Right soft key to activate zoom function. Digital zoom can be used for close up of features and image focus. Icon "Z" displayed in up right corner of display when active.
	Short	Edit capture area	Press Middle key to enter "Edit capture area" function and move image area to center of the screen.
	Long	Open Menu	Enter camera menu by pressing Right soft key for longer than 1s.
Middle key	Short	Edit focus window	When focus window is visible it is possible to move it using arrow keys to better capture the wanted area.
	Long	New patient folder	If multiple patients are examined during a same session, it is recommended to create a new file folder for each patient's images. New folder is created by pressing middle key for 3 seconds. Icon P at the top of the screen indicates number of the current patient folder. If the current folder does not have any images in it, a new folder cannot be created.
Left/Right arrow	-	Change brightness	Use left and right arrow keys to adjust capture light brightness. Aiming light brightness is adjusted in menu.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate. The Window returns to original position when camera is put to cradle, turned off or optics module detached.
Up/Down arrow	-	Focus manually	Use up and down arrows to focus manually.
	-	Zoom In / Out	Zoom in using arrow key up. Zoom out using arrow key down. There are four zoom levels: 1,2,4 and 6.
	-	Move AF window	Move focus window left and right after pressing Middle key to activate.

Table below includes explanations of the DF settings tab for general imaging:

Setting	Values (default bolded)	Purpose
Capture mode	Still / Video	Use left and right arrow keys to choose between still capture and video capture.
Focus window	Visible /Hidden	Use left and right arrow keys to choose between having focus window visible or hidden.
Shoot mode	Normal / Auto	In Auto mode camera takes picture automatically after focusing. In Normal mode user must press shutter button to second position to take picture after focusing.
Zoom cropping	On /Off	When turned on camera will save the zoomed area only. When turned off camera will save the whole image area even when zoom is used.

Capture mode

Both still images and video can be taken with the Pictor VP1HAND camera. Capture mode can be chosen in OTO menu and when using VP1OTO otoscopic module from left soft key. When taking video the shutter button must be held down while taking the video. The video recording will stop once the shutter button is released.

Focus Window

Focus Window help user position the image. The Focus Window can be moved on the screen by first pressing Middle key until icon “F” appears in up right corner of display and then using the arrow keys when aiming.

Shoot mode

Shoot mode function can be used when autofocus is enabled. There are two shoot modes to choose from: normal and auto.

In normal mode the camera will focus when shutter button is pressed half way down and take a picture when shutter button is pressed all the way down.

In auto mode when shutter button is pressed the camera will focus and take a picture automatically.

Zoom cropping

With zoom cropping on the camera will save the zoomed area instead of the whole image area. When zoom cropping is turned off then camera will save the whole image area instead of the area that is visible on the camera screen when user has zoomed in.

Camera stores selected menu settings when it is powered off.

13. Error messages

Volk Pictor VP1HAND will display error messages about the limitations of the usage. Error message is always displayed with explanatory message providing information about possible actions.

Following image is an example of an error message displaying information about recharging the device:

List of the all possible error messages:

Error message:	What to do:
Battery very low	You should consider charging the device
Memory almost full	You can store only a few more images or video before the storage is full
Memory full	You cannot store any more images or videos
Optics type not detected	Reconnect optics lens. Contact maintenance if lens does not connect.
Optic failure. Please detach the optic and restart the camera	Restart camera and reconnect optics lens. Contact maintenance if lens does not connect.
Memory not found	Open battery cover and check the connection of SD card.
Please reattach battery or change battery to a new one.	Battery is either not well in place or has been damaged. Try to reattach battery or change it to a new one.
Optics error detected. Please contact service	You should send the device to service for repair.

14. Cleaning instructions

Pictor is a precision optical instrument that should be handled with care. Please note following cleaning instructions:

- Shut down device before cleaning it
- Remove cradle from mains before cleaning it
- Disinfect housing with soft cloth moistened with alcohol. Avoid touching system connectors in the handset and cradle.
- If acetone based products are used, wait for cleaning agent to dissolve before starting up the device or connecting cradle to the mains.
- Lenses may be cleaned with cleaning cloth.

Pictor is not intended to be sterilized.

Clean optics and silicon support before each use on a new patient:

- Disinfect silicon support with soft cloth moistened with alcohol (70% ethyl alcohol), or
- Soak silicon support in glutaraldehyde based solution.

If replacement for silicon support is needed, please contact Volk or authorized Volk distributor.

Clean dermatoscope glass before each use on a new patient:

- Disinfect glass with soft cloth moistened with alcohol (70% ethyl alcohol), or
- Remove glass and soak it in glutaraldehyde based solution.

If replacement for the dermatoscope glass is needed, please contact Volk or authorized Volk distributor.

15. Device maintenance

Pictor contains rechargeable Ni-MH battery pack. Service life of the battery is approximately 1-2 years. When battery is at end of its service life, usage time of the device goes down.

Appendix B gives instructions for battery replacement.

There are no other maintenance procedures that can be carried out by the user. All servicing and repairs other than replacing the battery must be carried out by Volk or Volk certified service facilities and service personnel. Volk will make available work instructions to repair those parts of medical electrical equipment that Volk has designated as repairable by service personnel.



CAUTION:

No modification of this equipment is allowed.

CLASS 1 LASER PRODUCT

Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure



CAUTION:

If there are breaks in the device covers or other visual defects, contact Volk or authorized Volk distributor.

16. Technical description

CAMERA:

Type:	Pictor Handset VP1HAND
Image sensor:	CMOS, 5.0 Megapixels
Image memory type:	1-2 GB, micro SD card.
Display:	2.4", TFT-LCD, 262 000 million colors, antireflective coating
Image format:	JPEG (file extension: jpg)
Video format:	MPEG-4 and MPEG-1
Connectivity:	Computer with USB port
Operating systems:	No driver installation needed.
Dimensions:	82.30(w) x 166.50(h) x 66.50(d) mm
Weight:	400 g
Battery:	Rechargeable Ni-MH Cylindar cell, HR4U 700 AAA, 4.8 V, 1.0 Ah User can change battery. Batteries provided by Volk.
Usage time:	1h 30min with full battery



CHARGING CRADLE:

Type:	Pictor Cradle
Dimensions:	170(w) x 35(h) x 150(d) mm
Weight:	380 g

Switching power supply connected to cradle:

Type: CINCON TR10R090, Input: 100-240 V ~0.4A 47-63 Hz, Output: 9V, 1.1A, 10 W

USB cable: Type A to mini B, high-speed, unshielded, length 1.8 m

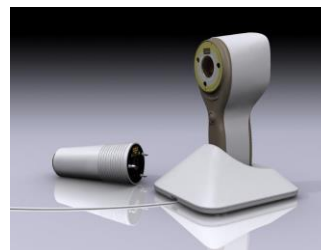


CAUTION:

It is only allowed to attach Battery and Power source provided into the Cradle. If you need replacement to the Battery or Power source, please contact Volk or authorized Volk distributor.

NON-MYDRIATIC OPHTHALMIC MODULE VP1RET CONNECTED TO THE PICTOR HANDSET VP1HAND

Type:	Pictor VP1RET
Intended use:	Digital ophthalmoscope. Intended to capture digital images and video of the fundus of the human eye.
Illumination:	Infrared LED for targeting Visible white LED for imaging, 10 illumination brightness levels
Field of view:	45°
Diopter compensation:	- 20 D to + 20 D
Image resolution:	1920 x 1440 px
Dimensions:	132.1 x 55.2 mm
Weight:	180 g



EXTERNAL OPHTHALMIC MODULE VP1ANT CONNECTED TO THE PICTOR HANDSET VP1HAND

Type:	Pictor VP1ANT
Intended use:	Digital external ocular optics module. Intended to capture digital images and video of the surface of the human eye and surrounding areas.
Illumination:	Visible white and cobalt blue LED for imaging, 10 illumination brightness levels
Image resolution:	2560 x 1920 px
Dimensions:	79 x 70 mm
Weight:	80 g



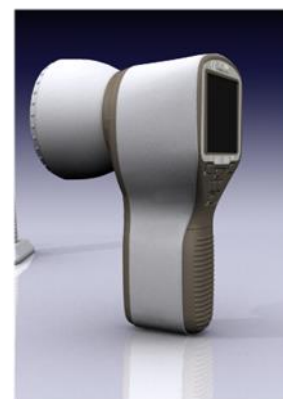
DIGITAL DERMATOSCOPE VP1DERM CONNECTED TO THE PICTOR HANDSET VP1HAND

Type: Pictor VP1DERM
Intended use: Digital dermatoscope. Intended to capture images of the skin.

Illumination: Light ring of 24 LEDs

Image resolution: 2560 x 1920 px
Image size on skin: 30 x 22 mm

Dimensions: 60 x 77mm
Weight: 150g



OTOSCOPIC MODULE VP1OTO CONNECTED TO THE PICTOR HANDSET VP1HAND

Type: Pictor VP1OTO
Intended use: Imaging of ear canal and tympanic membrane

Image resolution: 2560 x 1920 pixels

Dimensions: 49.2 x 45.5 mm
Weight: 80 g

Main features: Integrated LED illumination
Insufflation port for pneumatic otoscopy
Disposable and reusable speculum diameter range: 2.5 - 5



ENVIRONMENTAL CONDITIONS FOR USE, STORAGE AND TRANSPORTATION:

IP Code: IPX0 (Equipment not protected against the ingress of water)

Intended to be use indoors:

Temperature, use: + 10 °C to 35 °C

Relative humidity, use: 10 % to 80 %

Please note also EMC information given in Annex A.

Temperature, storage - 10 °C to 40 °C

Relative humidity, storage: 10 % to 95 %

NOTE: If stored over 1 month, it is recommended to remove battery. Appendix B gives instructions for removing the battery.

Transported in protective aluminium carrying case:

Temperature: - 40 °C to + 70 °C

Relative humidity: 10 % to 95 %

Atmospheric pressure: 500 hPa to 1060 hPa

Sinusoidal vibration: 10 Hz to 500 Hz: 0,5 g

Shock: 30 g, duration 6 ms

Bump: 10 g, duration 6 ms

SERIAL NUMBERING:

Label indicating serial number of the Handset is attached to the Warranty certificate and in the sticker next to system connector. Warranty certificate is part of this user's manual

Serial number of the cradle is in a sticker attached to the underside of the cradle.

Serial numbers of the attachable modules are attached to the modules and also to the Warranty certificate.

Year of manufacture is can be found from the serial number (digits 3 to 4).

SW version is displayed in the device menu.

EXPECTED USAGE LIFE OF PICTOR:

There are no strict limitations about expected usage life of Pictor. Usage life is approximately five years.

DISPOSING OF PICTOR:

Do not dispose Pictor as unsorted municipal waste. Prepare Pictor for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

For more specific information, please contact Volk or your authorized Volk distributor.

17. Warranty

Volk Optical gives device a 1 year warranty for the parts and labor. Warranty for battery is 6 months.

Submitting claim:

Any claim under this warranty must be submitted in writing before the end of warranty period to Volk Optical. The claim must include a written description of the problem.

Warranty does not cover:

Products that have been subjected to abuse, accident, alternation, modification, tampering, misuse, faulty installation, lack of reasonable care, repair or service in any way that is not contemplated in the documentation of the product, or if the model or serial number has been altered, tampered with, defaced or removed. Warranty does not cover damage caused by dropping the device or damage caused by normal wear and tear. Any issue related to the labels attached to the device coming off are not covered by warranty. Repair or service done by non Volk certified service facility is not covered by warranty.

Appendix A

Electromagnetic compatibility information



MEDICAL ELECTRICAL SYSTEM needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL SYSTEM.

Pictor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.

Manufacturer's declaration – electromagnetic immunity:


Pictor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	± 2 kV, ± 4 kV, ± 6 kV indirect contact ± 2 kV, ± 4 kV, ± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for AC power supply ±1 kV for serial cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	± 1 kV for AC power supply, 1 Phase without Protective Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Manufacturer's test shows conformance to the requirements of the IEC 61000-4-11/EN 61000-4-11	Mains power quality should be that of a typical commercial or hospital environment. If the user of Pictor requires continued operation during power mains interruptions, it is recommended that Pictor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity:

Pictor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of Pictor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/M	<p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz,</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Pictor is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Pictor.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Manufacturer's declaration – electromagnetic emissions:

Pictor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emissions test	Compliance level	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Pictor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Pictor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and Pictor:

Pictor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Pictor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Appendix B - Replacing the battery

Battery pack is specially designed and manufactured for this device. Volk and authorized Volk distributors provide suitable battery packs. Labels on the battery and inside the battery cover display following information:

NiMH battery
4/HR-4U AAA
4.8V/1000 mAh

Procedure for replacing battery



Open the battery compartment cover by pushing and tilting the snap through the hole next to the connector in the bottom of the device. A pen, screwdriver or similar device can be used to assist in opening the cover.



Remove the battery compartment cover by lifting it up.



Remove old battery. Squeeze battery wires with fingers and pull the connector out from its socket.



Put the new battery in the same position and attach the connector to its socket.

Replace the battery compartment cover and secure it in place by snapping it firmly to place.

Ordering Information:

Orders may be placed with the Authorized Volk Distributor in your region. Authorized Distributor contact information is available directly from Volk.

Volk Optical Inc.
7893 Enterprise Drive
Mentor, Ohio 44060
USA

Toll free within the United
States: 1-800-345-8655
Phone: 440 942 6161
Fax: 440 942 2257
Email: volk@volk.com
Website: www.volk.com

EU REPRESENTATIVE

The Volk authorized representative based
in the European Union (EU) is:

Keeler Limited
Clewer Hill Road
Windsor
Berkshire SL4 4AA U.K.
Tel: +44(0) 1753 857177



Note: This product complies with current required standards for electromagnetic interferences and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

Members of the European Union should contact their authorized Volk Distributor for disposal of this unit.



Certificate
FM 71461



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