

USER'S MANUAL Volk Pictor Plus Digital Imaging Device

THIS SALES PACKAGE INCLUDES:

Pictor Plus camera with optics lenses and accessories:

Model:	Description:	Accessories
Retina Module (VP2RET)	Module for eye fundus imaging	eye cup, quick user guide
Anterior Module (VP2ANT)	Module for exterior ophthalmic imaging	
Imaging handset (VP2HAND)	Handset for general imaging	
Cradle (VPCRADLE)	For data transmission and battery charging	USB cord, power unit

In addition, the sales case includes:

- (2) Batteries
- Cleaning cloth
- User manual

NOTE: Refer to the Instructions for Use page on the Volk website for the most current version of the user manual: www.volk.com/ifu

The following accessory can be purchased separately:

 Pictor Plus Slit Lamp Adapter (VP2SLM) that enables the camera to be used as stationary imaging tool.

QUICK START GUIDE

What to do before the first use:

- 1. Remove the Volk Optical Pictor Plus from the sales package and check that all parts are undamaged.
- 2. Install Battery as instructed in Appendix B of this manual.
- 3. Place the cradle on a desk next to the PC (personal computer).
- 4. Connect the USB cable to the PC.
- Connect the power cable's plug into the wall electrical outlet
- 6. Place Pictor Plus on 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.

NOTE: Camera will not automatically power up in the cradle without the power cable. User needs to press the power button.



Guideline for placing the camera to the cradle:

The camera will fit into the cradle when it is held straight while placing it. Excessive force must be avoided in order to prevent the camera and cradle connectors from breaking.



Guideline for battery and device storage:

If the battery is stored out of the camera for a long period of time, ensure that the battery is fully charged before storage. During storage, the battery must be recharged occasionally (e.g., every 3 - 9 months).

IM-071 Rev H Page 2 of 51



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

Device should not be used when battery cover is open.

IM-071 Rev H Page 3 of 51

TABLE OF CONTENTS

QUI	CK S	TART GUIDE	2
TAB	LE O	F CONTENTS	4
1	IND	ICATIONS FOR USE	5
2	ESSE	ENTIAL PERFORMANCE	6
3	CON	ITRAINDICATIONS FOR USE OF THE EYE OPTICS RETINA MODULE VP2RET AND	THE EYE
	OPT	ICS ANTERIOR MODULE VP2ANT	7
4	WAI	RNINGS AND CAUTIONS	8
5	IMP	ORTANT SYMBOLS	9
6		TS OF THE DEVICE	
7	USA	GE ENVIRONMENT REQUIREMENTS	15
8	OPE	RATING INSTRUCTIONS	16
8	.1.	Preparations	
8	.2.	Connection to a PC	
8	.3.	Basic use – starting up, shutting down, and taking an image	17
8	.4.	Attaching and detaching optics module	18
	.5.	Device Menu	
	.6.	Patient List editor	
	.7.	Adjusting focus and automatic focus	
	.8.	Patient Information	
_	.9.	Reset button	
		INAL IMAGING USING OPTICS MODULE VP2RET	
_	.1.	Steps for Retinal Imaging:	
		IMAGING USING ANTERIOR OPHTHALMIC MODULE VP2ANT	
		Steps for Eye Surface Imaging:	
		OR MESSAGES	
12	_	ANING INSTRUCTIONS	
13		ICE MAINTENANCE	_
14		HNICAL DESCRIPTION	
15		RRANTY	
	END		
ΔPP	ENIDI	IX R REPLACING THE RATTERY	49

1 INDICATIONS FOR USE

Pictor Plus is a medical digital camera that is used with dedicated optic lenses intended to take images of the eye fundus, and surface of the eye for diagnostic purposes.

Supported optic lenses and their intended uses are:

Component:	Description:		
VP2RET	Module for fundus imaging. The Pictor Plus VP2HAND digital camer with the VP2RET optics module is intended to capture digital images and video of the fundus of the human eye.		
VP2ANT	Module for exterior ophthalmic imaging. The Pictor Plus VP2HAND digital camera with the VP2ANT optics module is intended to capture images and video of the surface of the human eye and surrounding areas.		

The device may only be operated by persons who have been properly trained or who have the required knowledge and experience to do so.

IM-071 Rev H Page 5 of 51

2 ESSENTIAL PERFORMANCE

The essential performance of Volk Pictor Plus camera is to take images and video for consultation and documentation purposes with safe illumination levels according to the standard ISO 15004-2:2007.

IM-071 Rev H Page 6 of 51

3 CONTRAINDICATIONS FOR USE OF THE EYE OPTICS RETINA MODULE VP2RET AND THE EYE OPTICS ANTERIOR MODULE VP2ANT

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 what is needed 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, adults, 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.

Pictor Plus VP2RET and VP2ANT are classified as Group 2 based on standard ISO 15004-2:2007. The daily usage time and maximum allowed number of pulses is calculated based on optical classification results according to standard ISO 15004-2:2007.



CAUTION:

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after:

Maximum number of pulses (still images) allowed daily:

- VP2RET: 6300 pulses (still images) / eye
- VP2ANT: 250 pulses (still images) / eye

Total daily usage time for continuous light (video usage time and aiming light duration) shall be limited to:

- VP2RET: 1 hour 30 minute video usage / eye
- VP2ANT: 8 minute video usage / eye

IM-071 Rev H Page 7 of 51

4 WARNINGS AND CAUTIONS



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



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



Connection between the camera and the workstation is USB and/or Wi-Fi. Any authorization procedures should be carried out in the workstation.



Images and videos can be copied from camera to workstation via USB and/or Wi-Fi, and then viewed in the workstation.



USB write protection is on by default. When protection is on this feature will prevent writing to camera memory card from PC when connected to the cradle.



USB connection works without power cable. There is no USB charging in Pictor Plus camera.



No modification of this equipment is allowed.

IM-071 Rev H Page 8 of 51

5 IMPORTANT SYMBOLS

Symbol	Description
CE	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.
C E 2797	CE mark with notified body identification number indicates a Class IIa product.
i	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.
	WARNING Indicates a hazardous situation which could result in patient injury, harm or death if the appropriate safety precautions are not followed.
\triangle	CAUTION: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
*	Type BF applied parts. Applied part is a part of Pictor Plus that in normal use necessarily comes into physical contact with the patient.
⊕ ⊕ ⊕ 9V / 1.1A	Charger polarity symbol, voltage, and power.
	The symbol indicating separate collection for Waste Electric and Electrical Equipment per Directive 2002/96/EC.
((·•)))	The symbol indicating that the device is capable of wireless data communication based on the 802.11 IEEE network standard. When using Wi-Fi functionality, interference may occur in the vicinity of equipment.
Est Operation Co. Market.	Sticker at the front of the device indicating Volk Optical's address, integrated general imaging optics focal length, and F-number.

IM-071 Rev H Page 9 of 51

Symbol	Description
	Keep Dry Indicates a medical device that needs to be protected from moisture
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully.
F	Use no hooks Absolutely no hand hooks should be attached to pull the parcel
	Keep away from sunlight Indicates a medical device that needs protection from light sources.
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

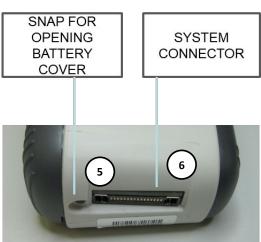
IM-071 Rev H Page 10 of 51

6 PARTS OF THE DEVICE

- 1. Bayonet connector
- 2. Bayonet hole
- 3. Optics release button
- 4. Dual action shutter

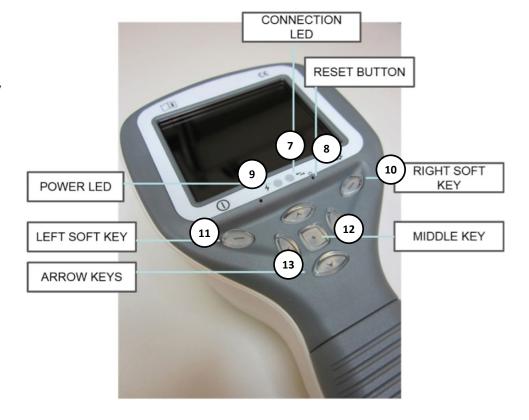


- 5. Snap for opening battery cover
- 6. System connector



IM-071 Rev H Page 11 of 51

- 7. Connection LED
- 8. Reset button
- 9. Power LED
- 10. Right soft key
- 11. Left soft key
- 12. Middle key
- 13. Arrow keys



CRADLE:

14. Cradle docking connector



- 15. USB cord
- 16. Power cord



IM-071 Rev H Page 12 of 51

SOFT KEY INDICATORS:

Position	Indicator	Purpose
Left soft key	(1)	To power on the device To power off the device, with long press
Right soft key	O	Open menu with long press

LED INDICATORS:

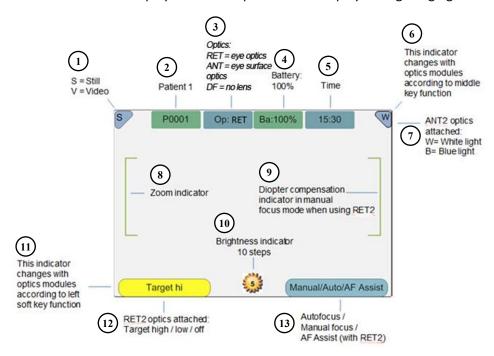
The recharging and connection to PC is indicated with green (charging) and blue (connection) LED-lights:

Position	Indicator	Purpose
Left LED-indicator Green	4	Active when device is powered on, blinking when charging in cradle
Right LED-indicator Blue	₽	Active when device is sitting in the cradle and connected to a PC

IM-071 Rev H Page 13 of 51

GRAPHICAL INDICATORS:

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



- 1. S=Still, V=Video
- 2. Folder number
- 3. Optics: RET (eye), ANT (eye surface), FA (angiogram), DF (no lens)
- 4. Battery level
- 5. Time
- 6. Variable indicator (changes with optics module according to middle key function)
- 7. Variable indicator with ANT optics attached: W=white light, B=blue light
- 8. Zoom indicator
- 9. Diopter compensation indicator in manual focus mode with RET optics attached
- 10. Brightness indicator
- 11. Variable indicator (changes with optics module according to left soft key function)
- 12. Variable indicator with RET optics attached: Target hi, Target low, Target off
- 13. Focus mode: Manual/Auto/AF Assist with RET optics attached

IM-071 Rev H Page 14 of 51

7 USAGE ENVIRONMENT REQUIREMENTS



CAUTION:

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

Pictor Plus is intended to be used inside; within a normal room temperature and a normal humidity environment. Do not use Pictor Plus in an environment where there is a possibility for water to condense on or inside the Pictor Plus. The type of power supply required is indicated in the Technical Description section.



CAUTION:

It is only allowable to attach the USB cable and power source provided in the sales package into the cradle. If you need replacements to the USB cable or power source, then please contact the Manufacturer or your own Retailer.

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

Place PC and cradle outside of 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 running either Microsoft Windows 7®, Windows 8® and Windows 10®. The device does not need any drivers to be installed on the computer.

Writing to the SD card from a PC is not enabled by default.

The device can be used with all major patient database applications supporting both textual and image data recording.

The device must be used according to this manual, quick reference guide, and/or information found on Volk Optical's website www.volk.com.

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

IM-071 Rev H Page 15 of 51

8 OPERATING INSTRUCTIONS

This chapter gives instructions for using the device. More specific instructions for using optics lenses are given in the optics lens specific chapters.

8.1. Preparations

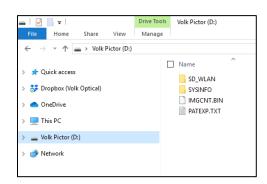
Pictor Plus is both charged and connected to a PC using the provided cradle. When Pictor Plus is not used, it may be stored in the cradle. Storing the device in the cradle is not harmful for the battery because the battery is charged only when the charge has dropped below a certain limit.

To connect Pictor Plus to the cradle, gently place it into the connector hole. The device can be connected to the cradle with optics attached.

8.2. Connection to a PC

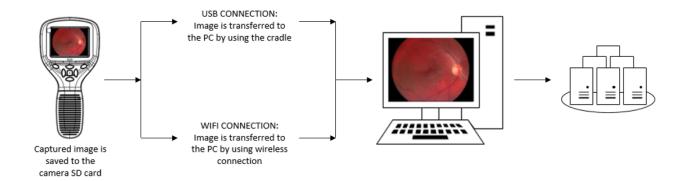
Image data transfer method to a PC is similar as with a digital camera.

When connected to a PC running Microsoft Windows 7° , Windows 8° or Windows 10° operating system, displays a drive letter for Volk Pictor. Simply open the folder to view and then store files to the hard disk of the PC.



Writing to the SD card from a PC is not enabled by default.

WIFI functionality enables wireless image transfer from camera to PC. Image transmission system is shown below:



IM-071 Rev H Page 16 of 51

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

The device is powered on by pressing the left soft key.

Pictor Plus verifies if image data is to be 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 when using device with a new patient.

The device offers the possibility to edit the current patient information.

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

Still image is captured by fully depressing the dual action shutter to the second position. When set to Video mode, video is captured by keeping the dual action shutter pressed down in the second position.

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

To transfer images to a PC, place the device into the cradle. The image transfer and charging is indicated with green and blue LED lights and text on the LCD screen. In case the WIFI connection is active, images are transferred to the PC automatically.

NOTE:

If images are corrupted or not transferred to the PC, the original images are saved to the memory card. Please try again to transfer images to the PC via USB.

The device is powered off by keeping the left soft key pressed down for over 1 second.

NOTE:

When device is powered on, powered off or goes to standby mode the camera focus motor may make a sound. This sound is normal and is not a sign of any damage or problem.

IM-071 Rev H Page 17 of 51

8.4. Attaching and detaching optics module



CAUTION:

Optic modules used with Volk Optical Pictor Plus must include text "PICTOR PLUS" or "PICTOR". Please do not attach other objects to the bayonet connector.

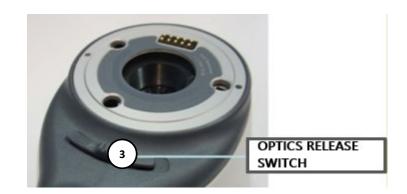
Optics are attached by placing it in front of the bayonet area of the device. Three bayonet legs are placed on the holes and optics is pressed firmly to lock into the device.

- BAYONET LEGS

 BAYONET HOLES
- 1. Bayonet legs
- 2. Bayonet holes

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

3. Optics release switch



8.5. Device Menu

The menu is opened by pressing the right soft key 🌣 for 1 second.

The menu has six tabs. One is for device settings, such as language selection. There is one tab for retinal imaging (RET), fundus angiogram imaging (FA), anterior eye imaging (ANT), and general imaging (DF).

The arrow keys are used to move between tabs: use the arrow up key until tab is active and use left and right arrow keys to change active tab. A light blue color indicates an active tab.

The arrow keys change values in the menu. An active value is indicated with a light blue color. Changed values are saved by using the left soft key ("Ok") and cancelled by pressing the right soft key ("Cancel"). Some values are confirmed by pressing the middle key.



IM-071 Rev H Page 18 of 51

The table below includes explanations of the device settings tab:

Setting	Values (default bolded)	Purpose
Draviou imagas	Ole	To preview the images on the camera, press the
Preview images	Ok	middle button.
		To create a new patient folder, press the middle
New patient folder	Ok	button. A new patient folder can also be created in
		live view by long pressing the middle key.
Erase image memory	Ok	Select the middle button to erase images and videos
Liase illiage illelilory	OK	from the camera SD card.
Edit patient list	Ok	Press the middle key to edit patient list.
Patient information	On/ Off	Enable or disable patient information linking.
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.
	ENG-FIN-FRA-GER-	Use left and right arrow keys to select camera
Select language	ITA-JPN-POR-SPA- ZHO	language.
		language.
	On/Off	When enabled, writing to SD card is not allowed while
USB write protection		the device is in the cradle. This feature helps prevent
		any viruses getting from the PC to the camera.
Video file format	MPEG4/MPEG1	Use left and right arrow keys to select video file
video ille format	IVIPEG4/IVIPEG1	format.
Image transfer	UMS/WIA	Use WIA for automatic and UMS for end-user
method		activated image transfer. UMS can be used in most
		cases.
Restore factory	Ok	To restore all settings menus to factory defaults.
Setting		Activate using the middle key.
SD card firmware	Ok	To start SD card firmware update mode, press middle
update mode		button.
Date	DD-MM-YYYY	Use up and down arrow keys to set date.
Time	HH:MM	Use up and down arrow keys to set time.
Camera SW version	Show camera SW	Browse version information with left and right arrow
	version	keys.
Start query	Era. /Fol./None	Choose the startup query between memory erase,
AA/: wallana		new patient folder, or no query at all.
Wireless	On/Off	Enable or disable wireless connection
Wireless info	Ok	To view 'WLAN SSID' and 'WLAN Password', press
		middle button.

IM-071 Rev H Page 19 of 51

Preview images

Image preview is opened by selecting "Preview files" with the middle key. Images are browsed by using arrow keys. The display gives information about usage of the image preview.

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

Patient ID information can be edited in image browser.

New Patient Folder

A new patient folder is created by pressing the middle key when the "New patient folder" selection is active on the device menu. A new patient folder can also be created by pressing the middle key for 3 seconds when in the live view. If the current patient folder is empty, then a new folder cannot be created. Patient ID information can be edited after creating a new patient folder.

Erase Image Memory

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

Edit patient list

User can add or remove patients from patient list.

Patient information

Enable or disable patient information linking.

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 the camera screen can be enabled or disabled to the user's liking. The most essential icons, such as the menu icon, are always visible.

Sounds

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

Keyboard backlight

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

Language

The camera has nine different languages that the user can choose from. The default language is English and the language selection is always shown in English on the 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 PC when connected to the cradle.

IM-071 Rev H Page 20 of 51

Video file format

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

Image transfer method

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

Restore factory settings

By selecting "Activate" in the device menu, "Restore factory defaults" selection, the original factory settings will be returned.

SD card firmware update mode

If the device has WiFi functionality, SD card firmware can be updated by pressing middle button. The device must be placed on cradle for SD card firmware update. If PC prompts a message to insert the SD card, press any camera key to continue update.

Date

The date can be set using the left and right arrow keys. Move between day, month, and year by pressing the middle key. The date format is DD MM YYYY for English, Finnish, German, French, Italian, Spanish, and Portuguese. The date format is MM DD YYYY for Japanese.

Time

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

Camera SW version

This item in the device menu tells the camera software version.

Start query

The 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 the 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 the camera will go directly to live view upon start-up.

Wireless

By default, wireless connection is on. User can enable or disable wireless connection. When wireless connection is enabled, the wireless symbol is shown on display next to the battery level indicator.

Wireless info

Press middle key to view wireless connection information. 'WLAN SSID' and 'WLAN Password' are shown.

IM-071 Rev H Page 21 of 51

8.6. Patient List editor

Patient information usage can be enabled and disabled. There can be maximum 500 patients on the list. The name of the patient is shown in the lower right-hand side of the live view screen, above the right soft key if the current folder is linked to a patient.

8.6.1. Adding new patient

The user can add a new patient from the Device Menu by selecting Edit Patient list. The user can add the patient ID and patient name after choosing new patient. A new patient can also be added after creating a new folder.

8.6.2. Patient folder linking

The user can link or unlink a patient to and from a current folder (not earlier ones). It is possible to link 5 folders to each patient.

Linking can be done by:

- 1. Answering yes when prompted during the power on or lifting the device from the cradle,
- 2. Selecting erase image memory from menu,
- 3. Choosing link in the image browser, when folders and files are visible. The link key is grey and unresponsive if the current folder is not chosen. After a folder is linked to a patient, the folder is named by the patient,
- 4. Creating a new folder by long pressing the middle key or from the menu.
- 5. Chose 'yes' when the camera asks to 'choose patient for the folder'.

NOTE: Exiting from image browser is done by pressing left key.

8.6.3. Patient list exporting

The user can export a patient list via Wi-Fi. A new file is created containing a patient list with 16 Kbytes of padding bytes added to the end of file. The file is named pehhmmss.jpg (hh is current hours, mm minutes, and ss seconds). The file is written under the DCIM folder in the SD card. The file is exported over Wi-Fi.

A patient list can also be exported via USB. A patient list is written as a text file (patexp.txt) to the SD card root. If a patient list is modified in the camera (e.g., new patient created) or the SD card is erased, then the patient list is updated.

8.7. Adjusting focus and automatic focus

The camera has an autofocus function when the camera finds a correct focus place automatically. For VP2RET, a square indicator appears when focusing is finished. For VP2ANT, the focus window turns green when focusing is finished. Automatic focusing starts when the shutter is pressed half-way down. The focus mode can be changed by pressing the right soft key.

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

IM-071 Rev H Page 22 of 51

8.8. Patient Information

What Is Patient Information Entry?

The Pictor Plus has a feature that allows entry 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 is being imaged left or right can also be recorded.
- 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 (Low Red) = CC
 - Anterior Segment = Co

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 was selected for John Doe, then the Exif field would also contain:
 Side:Left
 - If the particular image for John Doe was 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

IM-071 Rev H Page 23 of 51

- Location 2: the jpeg filename
 - The jpeg filename has 8 characters with a ".jpg" extension.
 - The naming convention is dependent on whether the setting for mark side is active
 - o The first two characters are used either for marking the side or the type of image taken.
 - The last two characters of the jpeg filename are reserved for the module used to produce the image:

Module	Image type	File name structure - mark side active (left)	File name structure - mark side active (right)	File name structure - mark side inactive	Exif data code
RET	Normal	OSxxxxRE	ODxxxxRE	IMxxxxRE	Co
RET	Red Free	SGxxxxRE	DGxxxxRE	GRxxxxRE	RF
RET	Low Red	SCxxxxRE	DCxxxxRE	CCxxxxRE	CC
RET	Infrared	SIxxxxRE	DIxxxxRE	IRxxxxRE	IR
ANT	Normal	OSxxxxAN	ODxxxxAN	IMxxxxAN	Со

• The middle 4 characters are reserved as a counter for the number of images taken: 0000 to 9999, and then rolling over to 0000 again.

How Is the Patient Eye Side Marked?

When taking a photo, the "Mark Side" feature can allow you to mark the photo as the left or right eye. The marked side is indicated in the image file name, as noted in the table above, and the lower left corner of the image is marked with an OS for Left Eye or OD for Right Eye.

- While in the live view screen, hold the right soft key to open the Device Menu.
- Navigate to the RET tab and turn the "Mark Side" option ON.
- When taking a photo, you will be asked to specify the side.
- Press the left soft key to mark the image as the left eye or press the right soft key to mark it as the right eye.

How Is Patient Information Entered?

The Patient Information screen is displayed when you select the "New Patient" option in the Patient List. The Patient Information screen shows the Patient ID, Patient Name and 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."

- Editing the patient information
 - 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.

IM-071 Rev H Page 24 of 51

- Exit the editor screen by using the right soft key below the exit icon. This saves the entered patient information.
- o 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 List?

If you have selected "Fol." for the "Start query" option in the "Device" tab of the Device Menu, you will be given the prompt "Create a new folder for new patient images?" when powering on the Pictor Plus or removing it from its charging cradle.

- If you press the left soft key to answer "Yes", a new patient folder will be created in the Image Browser, in the "Preview Images" menu.
- After answering the first question, you will be asked "Choose patient for the folder?".
 - o Select Yes (left soft button) to proceed to the Patient List.
 - Select No (right soft button) to proceed to the live view screen.
- While in the Patient List, use the up and down arrow keys to select a patient name, select "New Patient" to enter the Patient Information screen to add a new patient to the list, or press the right soft key to select "No Patient" to return to the live view screen without assigning a patient to the current patient folder.
- This will set the patient information which will be assigned to the next images taken.

While in the camera live view screen:

- Use the right soft key (long press) to access the Device Menu
- Under the Device tab, the Patient List and Patient Information entry screen can be accessed from the "Edit patient list", "Preview images" or "New patient folder" icons
- By selecting "Edit patient list" and pressing the middle button, you will be able to edit the patient list.
 - Use the arrow keys to navigate to "New Patient", to go to the Patient Information screen where you can enter the information for a new patient to be added to the list.
 - To delete a patient from the list, use the arrow keys to select the desired patient, and then press the left soft key to "Delete" the selected patient.
 - When you have completed your changes, press the right soft key to "Exit" the Patient List and return to the Device tab of the Device Menu.
- From the "Preview images" icon, you can link the newest folder to a patient in the Patient List.
 - After selecting "Preview images", the Image Browser will show the folder names at the left and the file names of images in the selected folder at the right of the screen
 - In the Image Browser screen, use the arrow keys to navigate to a specific folder
 - When only a folder is selected, the folder name will be highlighted with white text (the filenames will be dark).

IM-071 Rev H Page 25 of 51

- When an image file is selected, that filename and its folder name will be highlighted with white text.
- While you have selected the newest folder, listed at the top of the folder list, press the right soft key under the "Link" icon to go to the Patient List. (If you are selecting a different folder, the "Link" icon will be greyed out.)
- After selecting the desired patient from the list, press the left soft key under OK to assign that patient name to the newest folder. Selecting "New Patient" will allow you to enter the Patient Information screen to add a new patient to the list and assign it to the newest folder.
 - This will display the selected Patient Name as the name of the newest folder in the Image Browser.
 - NOTE: This will not modify the Patient ID of the photos which already reside in that folder. This will only set the camera to assign the selected Patient ID for any new photos which will be taken next.
- When in the live view screen, the selected Patient Name will be displayed at the lower right corner, above the right soft key
- From the "New patient folder" icon, you can create a new patient folder and select the patient information to be assigned to the next images which are taken.
 - o Navigate to the "New patient folder" icon in the menu and select it with the middle key.
 - o The device will prompt "Create a new patient folder for new patient images?"
 - Select Yes (left soft key) if you 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.
 - o Next, the device will prompt "Choose patient for the folder?"
 - Select Yes (left soft key) to proceed to the Patient List.
 - Select the desired patient information or select "New Patient" to assign a new patient per the above instructions
 - The newest folder will be assigned the selected Patient Name and the next images to be taken will contain the selected Patient ID in their Exif
 - Select No (right soft key) to return to the device tab without assigning patient information to the newest folder.
 - For a quicker way to create a new folder, hold the middle button while in the live view screen. This will show the same "Create a new patient folder for new patient images?" prompt described above, allowing you to create a new folder without having to enter the Device Menu.

IM-071 Rev H Page 26 of 51

8.9. Reset button

Reset button can be used if device behavior is abnormal.

The reset button is located in a small opening under the display. The button is marked with circle O.

The reset button can be pressed with a thin object, such as a paper clip. The button needs to be held down for over 7 seconds.



9 RETINAL IMAGING USING OPTICS MODULE VP2RET

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

- Camera handset
- Attachable ophthalmic lens, Retina
- Eye cup for Retina
- Cradle for charging and image transfer

Pictor Plus Retina is intended for non-mydriatic imaging. This means that infrared is used for targeting an image to the eye fundus, and visible light is flashed when the image is taken. The pupil does not respond to the infrared light so the examination is convenient for the patient. Constant illumination can be selected under the RET tab if mydriatic drops are used. Pictures can also be taken using infrared light for both aiming and capturing.

Pictor Plus Retina has 9 internal fixation targets for the patient to fixate on while imaging. Below, will guide how to control the fixation lights.

9.1. Steps for Retinal Imaging:

- 9.1.1. The examination room should be as dark as possible.
- 9.1.2. It is recommended that both the patient and the examiner should be seated while taking the images.
- 9.1.3. 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, the focus needs to be adjusted:

- Hyperopia: camera is focused to distance by pressing the arrow up key. One click of the key is approximately 1 diopter.
- Myopia: camera is focused closer by pressing the arrow down key. One click of the key is approximately 1 diopter.

IM-071 Rev H Page 27 of 51

- 9.1.4. The aiming light is automatically turned on when the camera enters live view.
- 9.1.5. The middle fixation target is lit when pressing the left soft key and it provides a macula centered image. To change the fixation target, press the left soft key and use arrow keys to navigate between the 9 targets as shown in the graphics in the lower left corner of the display. If the fixation target is not required, ask the patient to look at a target on a wall 6 9 feet (2 3 meters) behind the operator.
- 9.1.6. Exposure is adjusted using left and right arrow keys. There are brightness levels from 0 to 10, the default value is 5, and typical levels are from 2 to 8. There are also low brightness levels 0.2, 0.4, 0.6, and 0.8 if brightness level 1 is too bright.
- 9.1.7. When using IR/White capture mode, changing the illumination brightness affects only the white capturing flash. If using IR/IR or White/White capture modes, both aiming and capturing light are changed.
- 9.1.8. The aim guidance circle on the screen guides the user when to take an image. When the retina is not fully in view the circle is red. Once the aim is good and the retina fully appears on the screen, the circle turns green indicating a good position for capturing the image.
- 9.1.9. Approach the eye starting from a 4-inch (10 centimeter) distance. If the internal fixation target is not used, the 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). The pupil is approached until the reflection from the eye fundus can be seen. The right imaging distance is about 0.8 inch (2 cm). The eye cup must be compressed approximately half-way down. The aim guidance circle on the display guides the user to take an image once it turns from red to green.

The camera is stabilized by keeping the outer side of the hand against the patient's forehead. An example of the correct usage position is shown below:

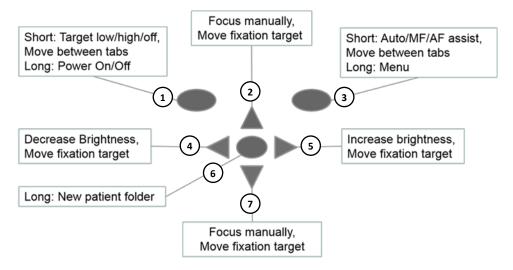


- 9.1.10. A still image is captured by pressing the shutter button all the way down. If half-press capture is enabled, a still image can be captured by pressing shutter button half-way. The captured image is displayed on the screen until the user clears the image by pressing the shutter button, left soft key, or right soft key.
 - Instant review can be enabled/disabled in the Pictor Plus optics menu.
- 9.1.11. An image can be zoomed during the instant preview by pressing the middle key. There are four zoom levels (1, 2, 4, and 8). Pressing the middle key activates the next zoom level. Move around the image by using the arrow keys. Scroll between images by using left and right arrow keys.

IM-071 Rev H Page 28 of 51

- 9.1.12. Video is captured by keeping the shutter button down. If half-press capture is enabled, video can be captured by pressing shutter button half-way. Video capturing is finished by pressing the shutter button all the way down.
- 9.1.13. If multiple patients are examined during one session, a new file folder can be created for each patient by pressing the middle key for 3 seconds.
- 9.1.14. Transfer images to a PC after capturing images. Images can be transferred to the PC when the camera is placed into the cradle. Pictor Plus works as any other digital camera.
- 9.1.15. To erase the image/video manually, choose menu, then preview images. There is the option to erase a specific image or a specific folder.
- 9.1.16. When the camera is removed from the cradle, it verifies if you would like to erase image data storage. It is recommended that image data storage is always erased before images of a new patient are captured.

The camera keys function as shown in the image below when the Pictor Plus Retina optics module is attached:



- 1. Short: Target low, target high, target off
 - Long: Power on, power off
- 2. Focus manually, move fixation target
- 3. Short: Focus Auto/MF/AF Assist, move between tabs Long: Menu
- 4. Decrease brightness, move fixation target
- 5. Increase brightness, move fixation target
- 6. Long: New patient folder
- 7. Focus manually, move fixation target

IM-071 Rev H Page 29 of 51

The table below provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Control fixation target level and selection	The fixation target is off by default and can be turned on by pressing the left soft key. The fixation target light has two levels: Low and High. If the patient cannot see the light on low level, then turn it up to high.
	Long	Power On / Off	The camera is powered on and off by pressing the left soft key for longer than 2 seconds.
Right soft	Short	Manual / Auto /AF Assist	Switch between focus modes by pressing the right soft key. Manual focus is on by default. Autofocus range is -11 to +3 diopters.
key	Long	Open menu	Enter the camera menu by pressing the right soft key for longer than 1 second.
Middle key	Long	New patient folder	If multiple patients are examined during the same session, it is recommended to create a new file folder for each patient's images. A new folder is created by pressing the middle key for 3 seconds. The P icon at the top of the screen indicates the 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 Select	Use left and right arrow keys to adjust capture light brightness. The icon above the left soft key must be selected (lighter color) to change brightness. Move between 9 internal fixation targets. The icon
d.1011		fixation target	above the left soft key turns to a lighter color when the fixation target selection mode is active.
Up / Down	-	Focus manually	When manual focus is active, use the up and down arrow keys to focus. Press the arrow up key when the patient has hyperopia. Press the arrow down key when the patient has myopia.
allow		Select fixation target	Move between 9 internal fixation targets. The icon above the left soft key turns to a lighter color when the fixation target selection mode is active.

The 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 move between still capture and video capture.
Half-press capture	On/ Off	Enable capture by pressing shutter button half-way.
Mark side	On/ Off	Mark side of the eye to the image data.
IR brightness	Low/ High	Aiming light brightness.
Red-free	On/Off	Saves a copy of an eye image using green color channel only.
Save IR image	On/ Off	Saves an image taken with IR light in addition to white light image when turned on.
Low red	On/ Off	Capture red reduced copy in addition to normal fundus image.

IM-071 Rev H Page 30 of 51

Setting	Values (default bolded)	Purpose
Illumination mode	IR/W, IR/IR, W/W	Use left and right arrow keys to select aiming and capture light source.
Automatic IR contrast	On/Off	Enable automatic IR contrast.
Target blinking	On/Off	Fixation target light can be set to constant if needed.
Capture setting in image	On/ Off	Enable or disable writing of capture settings to image.
Instant Review	On/Off	Instant review can be ON/OFF according to user need, as available in the RET optics menu. Instant review image can be changed from left and right arrow keys.

Capture mode

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

Half-press capture

It is possible to take images and video by pressing shutter button half-way.

Marking side

It is possible to mark which eye was imaged. Marking side is enabled from the menu. Side is marked to the file name and to the image, as well as the image data. For video files, side is only marked to the file name.

When marking side is enabled, the camera asks to select the side after each captured image.

- Identifiers used for normal eye images are OS for left and OD for right.
- Identifiers used for red-free images are SG for left and DG for right.
- Identifiers used for saved IR images are SI for left and DI for right.
- Identifiers used for low-red images are SC for left and DC for right.

IR brightness

IR brightness can be set to high or low depending on the color of the retina. For dark eyes, use high IR brightness.

Save Red-free

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

Save IR image

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

Low red

It is possible to capture a red reduced image.

Illumination mode

Illumination mode can be set to IR/W, IR/IR, or W/W. In IR/W 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/W mode whenever possible. In IR/IR mode, both aiming and image capture are done with infrared light. In W/W mode, aiming and image capture are done with white light.

IM-071 Rev H Page 31 of 51

Automatic IR contrast

Automatically adjust infrared live view brightness and contrast according to image content. Improves visibility of fundus features during aiming. Same contrast and brightness settings are applied to IR still captures.

NOTE: In IR/IR mode, IR brightness adjustment does not always directly affect the brightness on the screen when automatic contrast is enabled. This happens because the automatic contrast feature always tries to adjust the screen brightness to same level. The IR brightness setting still works, but the effect is only visible when the adjustment range of automatic contrast adjustment runs out. It is advisable to use the highest brightness that does not cause image saturation (pink or white "washed out" effect).

Target blinking

By default, the fixation target light is on with blinking illumination. If the patient cannot keep their eye targeted, then the light can be changed to constant to help focus on the target light.

Capture setting in image

It is possible to write brightness and diopter settings to an image. When enabled, this writes these settings to the lower right corner of the image.

Instant review

Instant review can be ON/OFF according to user need, as available in RET optics menu. When the reviewing zoom level is 1x, the user can change the image to be reviewed with left and right arrow keys. Images are shown in order Normal, Low-red, Red-free, IR.

NOTE: The camera retains selected menu settings while it is powered off.

10 EYE IMAGING USING ANTERIOR OPHTHALMIC MODULE VP2ANT

The Pictor Plus Anterior digital ophthalmic camera is intended to capture images and video of the surface of the human eye and surrounding areas. The device set for anterior imaging consists of:

- Camera handset
- Attachable ophthalmic lens, Anterior
- Cradle for charging and image transfer

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

10.1. Steps for Eye Surface Imaging:

- 10.1.1. Once the Anterior optics module is attached, the light source is chosen by pressing the left soft key.
- 10.1.2. Still or video image selection is made in the ANT menu.
- 10.1.3. It is recommended to use autofocus.
- 10.1.4. The aiming light is turned on by pressing the shutter key (in front of the device) half-way down.

IM-071 Rev H Page 32 of 51

- 10.1.5. Light is adjusted using left and right arrow key. There are brightness levels from 0 to 10, the default value is 5, and typical levels are from 2 to 8.
- 10.1.6. Place the optics module cup on the patient's eye. The patient can be asked to look in different directions depending on what area of the eye needs to be captured.

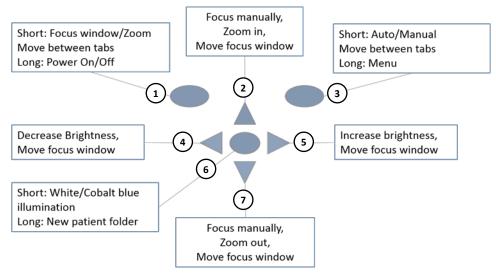
The camera is stabilized by keeping the outer side of the hand against the patient's forehead. An example of the correct usage position is shown below:



- 10.1.7. A still image is captured by pressing the shutter key all the way down. If half-press capture is enabled, a still image can be captured by pressing shutter button half-way. The captured image is displayed on the screen until the user clears the image by pressing the shutter button, left soft key, or right soft key.
 - Instant review can be enabled/disabled in the Pictor ANT optics menu.
- 10.1.8. An Image can be zoomed during the instant preview by pressing middle key. There are four zoom levels (1, 2, 4, and 8). Pressing the middle key activates the next zoom level. Move around the image by using arrow keys. Scroll between images by using left and right arrow keys.
- 10.1.9. Video is captured by keeping the shutter button down. If half-press capture is enabled, video can be captured by pressing shutter button half-way. Video capturing is finished by pressing shutter button all the way down.
- 10.1.10. If multiple patients are examined during one session, a new file folder is created for each patient by pressing middle key for over 3 seconds.
- 10.1.11. Transfer images to a PC after capturing images. Images can be transferred to the PC when the camera is placed into the cradle or images are automatically transferred wirelessly to the PC if Wi-Fi connection is active. Pictor Plus works as any other digital camera.
- 10.1.12. Manually erase the image or video by choosing menu, and then preview images. The specific image or the specific folder can be selected to be erased.
- 10.1.13. When the camera is removed from the cradle it verifies if you would like to erase image data storage. It is recommended that image data storage is always erased before images of a patient are captured.

IM-071 Rev H Page 33 of 51

The camera keys function as shown in image below when the Pictor Plus Anterior optics module is attached:



- 1. Short: Focus window, zoom, move between tabs Long: Power on, power off
- 2. Focus manually, zoom in, move focus window
- 3. Short: Focus Auto/Manual, move between tabs Long: Menu
- 4. Decrease brightness, move focus window
- 5. Increase brightness, move focus window
- 6. Short: White/Cobalt blue illumination Long: New patient folder
- 7. Focus manually, zoom out, move focus window

IM-071 Rev H Page 34 of 51

The table below provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Edit focus window, activate zoom	When the focus window is visible, it is possible to move it using the arrow keys to better capture the wanted area. Digital zoom can be used for close-up of features and image focus. Zoom value is saved to camera memory.
	Long	Power On / Off	Camera is powered on and off by pressing the left soft key for longer than 2 seconds.
Right soft key	Short	Manual / Auto / Activate Zoom	Switch between Auto and Manual focus by pressing the right soft key. Press the right soft key to activate the zoom function. Digital zoom can be used for close-up of features and image focus. Zoom value is saved to camera memory.
	Long	Open menu	Enter the camera menu by pressing the right soft key for longer than 1 second.
Middle key	Short	White / Blue	Choose between white and blue illumination by pressing the left soft key. Blue light can be used with fluorescent applied on the eye to reveal any cuts or defects.
	Long	New patient folder	If multiple patients are examined during the same session, it is recommended to create a new file folder for each patient's images. A new folder is created by pressing the middle key for 3 seconds. The P icon at the top of the screen indicates the 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.
		Move focus window	Move the focus window left and right after pressing the middle key to activate. The window returns to the original position when the camera is put onto cradle, turned off, or the optics module is detached.
Up / Down arrow	-	Focus manually	Use up and down arrows to focus manually.
		Zoom In / Out	Zoom in using the arrow up key. Zoom out using the arrow down key. There are four zoom levels: 1, 2, 4, and 6. The zoom value is saved to the camera memory.
		Move focus window	Move the focus window left and right after pressing the middle key to activate.

IM-071 Rev H Page 35 of 51

The 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.
Half-press capture	On/ Off	Enable capture by pressing shutter button half-way.
Focus windows	Visible/Hidden	Use left and right arrow keys to choose between having the focus window visible or hidden.
Mark side	On/ Off	Mark side of the eye to the image data.
Zoom cropping	On/Off	When turned on, the camera will save the zoomed area only. When turned off, the camera will save the whole image area even when zoom is used.
Instant Review	On/Off	Instant review can be ON/OFF according to user need, as available in the ANT optics menu. Instant review image can be changed from left and right arrow keys.

Capture mode

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

Half-press capture

It is possible to take images and video by pressing shutter button half-way.

Focus Window

The focus window helps users position the image. The focus window can be moved on the screen by first pressing the middle key until the F icon appears in upper right corner of display, and then using the arrow keys when aiming.

Shoot mode

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

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

In auto mode, when the shutter button is pressed all the way down, 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. Side is marked to the file name and to the image, as well as the image data. For video files, side is only marked to the file name.

When marking side is enabled, the camera asks to select the side after each captured image. The 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. By default, zoom cropping is turned off and the camera will save the whole image area instead of the area that is visible on the camera screen when the user has zoomed in.

IM-071 Rev H Page 36 of 51

Instant review

Instant review can be ON/OFF according to user need, as available in ANT optics menu. When the reviewing zoom level is 1x, the user can change the image to be reviewed with left and right arrow keys. Images are in showing order Normal, Low-red, Red-free, IR.

NOTE: The camera stores selected menu settings when it is powered off.

IM-071 Rev H Page 37 of 51

11 ERROR MESSAGES

The Pictor Plus will display error messages about the limitations of the usage. An error message is always displayed with an explanatory message providing information about possible actions.

List of the all possible error messages:

Error message:	What to do:	
Autofocus calibration needed	Please hold camera horizontal and press OK to calibrate.	
Battery failure	Remove battery completely from camera. Re-install or replace.	
Charging failure	Please remove and reconnect device to cradle.	
Image counter full	Copy images to safe location and then choose Erase image memory from device menu.	
Image storage not found	Please contact service for more information.	
Light source temperature too high	Please wait for camera to cool down. Cooling may take several minutes.	
Memory erasing failed	Please contact service for more information.	
Memory full	Memory is full, store images and erase memory card.	
Optic type not detected	Please re-attach optic.	
Optic communication failed	Please re-attach optic.	
Optic control failed	Please detach optic and restart camera.	
Patient list upload failed	Please verify list against instructions.	
System flash memory not available	Please contact service for more information.	
Low battery. Please Charge. Powering down.	Charge battery or change it to a new one.	
Failed to access image memory	Erasing image memory might help	
Previous startup did not finish successfully	Erasing image memory might help.	
Failed to change wireless password #	New password is invalid or the change otherwise failed. Retry to change the password. Contact maintenance if same error happens again. The number after the text is an error code that may be needed by customer service.	

IM-071 Rev H Page 38 of 51

12 CLEANING INSTRUCTIONS

Volk Optical Pictor Plus is a precision optics instrument that should be handled with care. Please note the following cleaning instructions:

- Shut down device before cleaning it
- Before cleaning the cradle, disconnect the its cables from electrical outlet and computer
- Disinfect housing with soft cloth moistened with alcohol (e.g. 70% ethanol). 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. Also, moist-cleaning tissue such as Hama Pro-Optic® cleaning tissue can be used.

Volk Optical Pictor Plus is not intended to be sterilized.

Clean the eye optics, eye surface of optics and eye cup before each use on a new patient:

- Disinfect eye cup with soft cloth moistened with alcohol (e.g. 70% ethyl alcohol), or
- Soak eye cup in glutaraldehyde-based solution, or hydrogen peroxide and peracetic acid solution such as Erisan OXY+
- Rinse the eye cup under running water
- Dry the eye cup (e.g. with clean paper towel) before subsequent use

If replacement for the eye cup is needed, please contact Volk Optical or your own retailer.

Eye cup should be replaced if/when:

- the eye cup is discolored
- the eye cup form is deteriorated
- the eye cup is shattered, cracked or disintegrated



CAUTION:

Clean eye cup before each use on a new patient to avoid contamination.

IM-071 Rev H Page 39 of 51

13 DEVICE MAINTENANCE

Pictor Plus contains a rechargeable Ni-MH battery pack. Service life of the battery is approximately 1-2 years. Battery needs to be replaced on planned intervals. 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 Optical or Volk Optical certified service facilities and service personnel. Volk Optical will make available work instructions to repair those parts of medical electrical equipment that Volk Optical has designated as repairable by service personnel.



CAUTION:

If there are breaks in the device covers or other visual defects, contact Volk Optical or a Volk Optical certified service facility.

IM-071 Rev H Page 40 of 51

14 TECHNICAL DESCRIPTION

CAMERA:

Type: PICTOR Plus Handset (VP2HAND)

Image sensor: CMOS, 5.0 Megapixels

Image memory type

(pre-May 2015): 4 GB, micro SD card

(May 2015 - June 2019): 8 GB, SD card (post-June 2019): 16 GB, SD card

Display: 2.4", TFT-LCD, 262 000 colors, antireflective coating

Image format: JPEG (file extension: jpg)

Video format: MPEG-4 and MPEG-1

USB Connectivity: PC with USB **WIFI Connectivity:** 802.11gn, WPA2

Frequency range: 2412 – 2462 MHz Max radiated power: 17 dBm

Operating systems: Windows 7[®], Windows 8[®], Windows 10[®]

No driver installation needed

Dimensions: 82.30(w) x 166.50(h) x 66.50(d) mm

Weight: 400 g

Battery: Rechargeable Ni-MH Cylinder cell, HR4U 700 AAA, 4.8 V, 1.0 Ah

User can change battery. Batteries provided by Volk Optical.

Usage time: 1h 30min with full battery

CHARGING CRADLE:

Type: PICTOR Plus Cradle (VPCRADLE)

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, 10W

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



CAUTION:

You are only permitted to attach the battery and power source provided in the sales package into the cradle. If you need a replacement for the battery or power source, please contact Volk Optical or your own retailer.

IM-071 Rev H Page 41 of 51

NON-MYDRIATIC OPHTHALMIC MODULE VP2RET CONNECTED TO THE PICTOR PLUS HANDSET VP2HAND:

Type: Pictor Plus Retina (VP2RET)

Intended use: Intended to capture digital images and video of the

fundus of the human eye.

Illumination: Infrared LED for targeting

Visible white LED for photographing 10 illumination brightness levels 9 red Internal fixation target LEDs

Maximum Luminance

output level towards eye: 95.8 cd/cm²

Field of view: 40°

Diopter compensation: - 20 D to + 20 D

Image resolution: 1536 x 1152 px (total 1.8 Mpix, informational area 1.41 Mpix)

Dimensions: 160x73mm

Weight: 310 g

EXTERNAL OPHTHALMIC MODULE VP2ANT CONNECTED TO THE PICTOR PLUS HANDSET VP2HAND:

Type: Pictor Plus Anterior (VP2ANT)

Intended use: Digital eye anterior 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

photographing

10 illumination brightness levels

Maximum Luminance

output level towards eye: 192 cd/cm²

Image resolution: 2560 x 1920 px

Dimensions: 79 x 70 mm

Weight: 90 g



IM-071 Rev H Page 42 of 51

ENVIRONMENTAL CONDITIONS FOR USE, STORAGE AND TRANSPORTATION:

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

NOTE: Intended to be use indoors.

Temperature, use: + 10 °C to 35 °C

Relative humidity, use: 10 % to 80 %

Atmospheric pressure: 800 hPa to 1060 hPa

NOTE: EMC information given in Annex A.

Temperature, storage - 10 °C to 40 °C

Relative humidity, storage: 10 % to 95 %

Atmospheric pressure: 500 hPa to 1060 hPa

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: $-40 \,^{\circ}\text{C} \text{ to} + 70 \,^{\circ}\text{C}$

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



CAUTION:

Do not leave the eye cup in direct sunlight as it may warm up and burn a patient's face when taking an image.

SERIAL NUMBERING:

The sticker indicating the serial number of the handset is attached to the warranty certificate and is the sticker next to the system connector. The warranty certificate is part of this user's manual.

The serial number of the cradle is on a sticker attached to the underside of the cradle.

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

The year of manufacture can be found from the serial number (digits 3 and 4).

The software version is displayed in the menu under the device tab.

EXPECTED USAGE LIFE OF THE PICTOR PLUS:

There are no strict limitations on expected usage life of the Pictor Plus. Usage life is expected to be approximately five years.

IM-071 Rev H Page 43 of 51

INTELLECTUAL PROPERTY RIGHT INFORMATION:

Microsoft Windows 7[®], Windows 8[®] and Windows 10[®] are trademarks of Microsoft Corporation.

Hama Pro-Optic is a trademark of Hama GmbH & Co KG.

Erisan OXY+ is a trademark of Farmos Ltd.

DISPOSING OF THE VOLK OPTICAL PICTOR PLUS:

Do not dispose of the Volk Optical Pictor Plus as unsorted municipal waste. Prepare the Volk Optical Pictor Plus 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.

Packaging materials: Sales case and transportation cardboard packaging should be retained for future relocation or repair. If you decide to dispose of the packaging material, submit it to a recognized collection system of recycling (Sales case consists of aluminum, plastic, foam and fabric).

For more specific information, please contact Volk Optical or your own retailer.

CONTACT:

If you wish to contact your local support personnel, please call 440-942-6161 or email volk@volk.com

15 WARRANTY

Volk Optical provides this device with a 1 year warranty for the parts and labor. The warranty for the battery is 6 months. Additional warranty is available for purchase from Volk Optical.

SUBMITTING CLAIM:

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

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 are not covered under warranty. The warranty does not cover damage caused by dropping the device or damage caused by normal wear. Any issue related to the stickers attached to the device coming off are not covered by warranty. Repair or service done by a non-Volk Optical certified service facility is not covered by warranty.

For customer support, please email volk@volk.com.

IM-071 Rev H Page 44 of 51

APPENDIX A ELECTROMAGNETIC COMPATIBILITY INFORMATION



Special precautionary measures apply to this device with regard to electromagnetic compatibility (EMC). If the essential performance of Pictor Plus camera is lost or degraded due to electromagnetic disturbances, it may cause unexpected or adverse operation of this device. If a malfunction cannot be rectified, please contact your local distributor or customer support at volk@volk.com.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. The device should not be operated in the vicinity of high-frequency surgical equipment.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pictor Plus camera, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

IM-071 Rev H Page 45 of 51

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY:

The Pictor Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Pictor Plus should assure 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	±8 kV contact ±15 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	±2 kV for AC power supply	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 differential mode ±2 kV common mode	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	0 % UT for 0.5 at 8 φ angles; 0 % 1 cycle; 70 % UT for 25 cycles; 0 % for 5 sec	0 % UT for 0.5 at 8 φ angles; 0 % 1 cycle; 70 % UT for 25 cycles; 0 % for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pictor Plus requires continued operation during power mains interruptions, it is recommended that the Pictor Plus be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IM-071 Rev H Page 46 of 51

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY:

The Pictor Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Pictor Plus should assure 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 & 6 Vrms ISM frequency	3 Vrms 150 kHz to 80 MHz & 6 Vrms ISM frequency	Portable and mobile RF communications equipment should be used no closer to any part of the Pictor Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $\mathbf{d} = 1.2 \sqrt{P}$ $\mathbf{d} = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $\mathbf{d} = 2.3 \sqrt{P} \text{800 MHz to 2.5 GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 6.0 GHz Pulse Modulation	GHz AM Modulation & 9–28 V/m 385 MHz to 6.0	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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^A , should be less than the compliance level in each frequency range ^B . Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 UT is the AC mains voltage prior to application of the test level

NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3 The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765–6.795 MHz; 13.553–13.567 MHz; 26.957–27.283 MHz and 40.66–40.70 MHz.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A) 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 theoretically 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 the Pictor Plus is used exceeds the applicable RF compliance level above, Pictor Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pictor Plus.

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

IM-071 Rev H Page 47 of 51

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS:

The Pictor Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Pictor Plus should assure that it is used in such an environment.

Emissions test	Compliance level	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	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	Is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supplements.	
Harmonic emissions IEC 61000-3-2	Not applicable		
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	network that supplies buildings used for domestic purposes.	

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE VOLK OPTICAL PICTOR PLUS:

The Pictor Plus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Volk Optical Pictor Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Volk Optical Pictor Plus 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	80 MHz to 800 MHz	800 MHz to 2.7 GHz	
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
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	

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (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.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IM-071 Rev H Page 48 of 51

APPENDIX B REPLACING THE BATTERY

A battery pack is specially designed and manufactured for this device. Volk Optical and Volk Optical's retailers provide suitable battery packs. The label on the battery displays the following information:

- NiMH battery
- 4.8V/1000 mAh

THE PROCEDURE FOR REPLACING THE BATTERY IS AS FOLLOWS:



1. Ensure that camera is powered off. Open the battery compartment cover by lifting from the notch in the bottom of the device with your finger. If the cover is tight, you may use a small tool like a pen by inserting it into the round hole between the cover and system connector



2. Remove the battery compartment cover by lifting it up.



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



4. To reattach the battery, carefully line up the holes in the battery's connector with the 4 pins in the handset battery connector, and gently press them together.



5. Replace the battery compartment cover and secure it in place by snapping it firmly into the handset.

IM-071 Rev H Page 49 of 51

Ordering Information:

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

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:

Rudolf Riester GmbH

Bruckstraße 31

72417 Jungingen

Germany

Email: info@riester.de Phone: (+49) 7477-9270-0 Fax: (+49) 7477- 9270-70



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

IM-071 Rev H Page 50 of 51



Volk Optical Inc.

7893 Enterprise Drive Mentor, Ohio 44060 USA

Phone: 440-942-6161
Toll free within the United States: 1-800-345-8655

Fax: 440-942-2257

Email: volk@volk.com
Website: www.volk.com

IM-071 Rev H Page 51 of 51