



USER'S MANUAL

Volk Pictor Plus Fluorescein Angiography (FA) Module

**For Use with:
Volk Pictor Plus**

THIS SALES PACKAGE INCLUDES:

Model:	Description:
Fluorescein Angiography (VP2FA)	Module for fundus fluorescein angiography imaging
IM-080	User Manual

QUICK START GUIDE

WHAT TO DO BEFORE THE FIRST USE:







Remove Volk Optical Pictor Plus Fluorescein Angiography module from the sales package and check that all parts are undamaged.

NOTE: For more detailed information on the use of the Pictor Plus Handset, VP2HAND, please consult Instructions for Use document IM-071.









INDICATIONS FOR USE

The Pictor Plus Fluorescein Angiography module VP2FA is a supported optics lens for the Pictor Plus Handset VP2HAND and is intended to capture digital images of the fundus angiograms of the human eye.

WARNINGS AND CAUTIONS

	Use only accessories and battery provided by Volk Optical with this product.
	Place PC and cradle outside the patient environment (at least 4 feet distance from the patient).
	Connection between camera and workstation is USB and/or WIFI. Any authorization procedures should be carried out in workstation.
	Images and videos can be copied from camera to workstation via USB and/or WIFI and then viewed in 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. In case device has WIFI functionality, USB write protection must be turned off.
	No modification of this equipment is allowed.



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 Plus that in normal use necessarily comes into physical contact with the patient.</p>
	<p>Used to highlight the fact that there are specific cautions associated with the device, which are not otherwise found on the label.</p>
 <p>9V, 1.1 A</p>	<p>Charger polarity symbol, voltage and power</p>
	<p>The symbol indicating separate collection for Waste Electric and Electrical Equipment per Directive 2002/96/EC.</p>
	<p>ME Equipment and ME SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labelled with the symbol for non-ionizing radiation.</p>
	<p>Sticker at the front of the device indicating Volk Optical's address, integrated general imaging optics focal length and F-number.</p>

PARTS OF THE DEVICE





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

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

ATTACHING AND DETACHING OPTICS MODULE

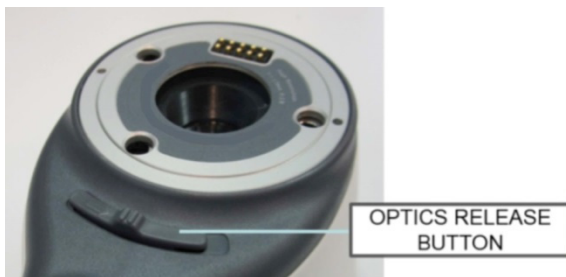


CAUTION:

Optic modules used with Volk Optical Pictor Plus must include text “PICTOR PLUS” or “PICTOR”. It is not allowed to 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 the device.



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

DEVICE MENU

- Menu is opened by pressing 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), fundus angiography (FA), 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.



Fluorescein Angiography Imaging Using Optic Modules VP2HAND & VP2FA

The Volk Optical FA digital ophthalmic camera is intended to capture digital images of the fundus angiography of the human eye. The device set for fundus angiography imaging consists of:

- Pictor Plus handset VP2HAND
- Attachable Pictor Plus FA module VP2FA
- Eye cup for Pictor Plus VP2ECUP
- Cradle for charging and image transfer VPCRADLE

Infrared is used for targeting image to the eye fundus and blue light is flashed when image is taken. Pupil does not respond to the infrared light so examination is convenient for the patient.

Pictor Plus FA has 9 internal fixation targets for the patient to fixate at while imaging. Below section will guide how to control the fixation lights.

STEPS FOR RETINAL 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.
3. When using Pictor Plus FA optics, the device should be mounted on a slit lamp base using Slit lamp Adapter, its mandatory to achieve good images.
4. 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 Diopters.
 - Myopia: camera is focused closer by pressing arrow key down. One click of the key is approximately 2 Diopters.
5. Aiming light is automatically turned on when camera enters live view.
6. The middle fixation target is lit when pressing left soft key and it provides a macula centred image. To change the fixation target press Left Soft Key and use arrow keys to navigate between the 9 targets as shown in the graphics in lower left corner of the display. If fixation target is turned off ask patient to look at a target in a wall 6-9 feet (2-3 meters) behind the operator.

7. 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. Changing illumination brightness affects only the blue capturing flash.
8. Aim help square on the screen guides user when to take image. When retina is not fully in view the square is red. Once the aim is good and retina fully appears on screen the Square turn's green indicating a good moment for capturing the image.
9. Approaching the eye is started from 4 inches (10 centimetres) distance. 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. Aim help square on the display guides to take image once it turns from red to green.

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:

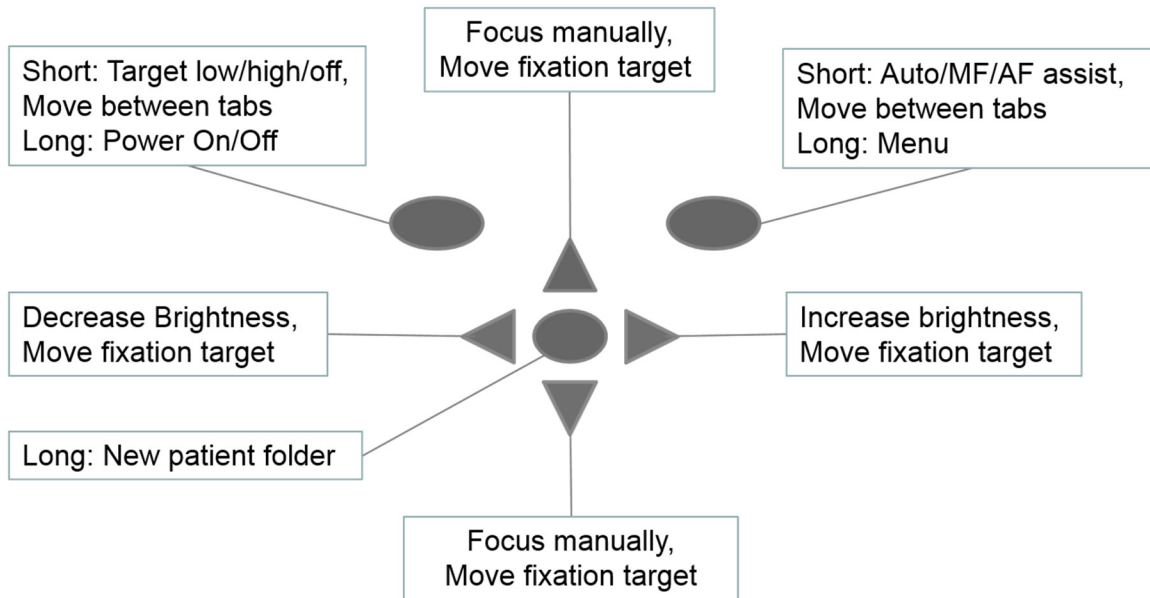


10. Still image is captured by pressing the shutter key all the way down. Video is captured by keeping shutter down. Taken image is displayed on screen until user clears the image by pressing shutter, left or right soft key. Image can be zoomed in instant preview by pressing middle key. There are four zoom levels. Pressing middle key activates the next level. Move around the image by using arrow keys.

This Instant Preview can be enabled/ disabled in the Pictor Plus FA optics menu.

11. If multiple patients are examined during one session, new file folder is created for each patient by pressing middle key for over 3 seconds.
12. Transfer images to a PC after capturing images. Images are transferred to the PC when camera is placed to the cradle. Pictor Plus works as any other digital camera.
13. 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 VP2FA optics module is attached:



Below table provides explanations for the key functions:

Key	Press	Function	Explanation
Left soft key	Short	Control Fixation target level and selection	Fixation target is off by default and can be turned on by pressing left soft key. Fixation target light has two levels: Low and High. If the patient cannot see the light on low level turn it up to high.
	Long	Power On / Off	Camera is powered on and off by pressing the Left soft key for longer than 2s.
Right soft key	Short	Manual / Auto	Switch between focus modes by pressing Right soft key. Manual focus is on by default. 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. Icon above left soft key must be selected (lighter color) to change brightness.
		Select fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.
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.
		Select fixation target	Move between 9 internal fixation targets. Icon above left soft key turns to lighter color when fixation target selection mode is active.

Table below includes explanations of the FA settings tab for fundus Angiography imaging:

Setting	Values (default bolded)	Purpose
Start Study		This enables the study to start. For every new study, user needs to go into the menu and start study to enable the study or Time counter.
Mark side	On/Off	Mark side of the eye to the image data.
IR brightness	Low/High	Aiming light brightness.
Instant Review	On/Off	Instant review can be ON/OFF according to user need, as available in FA Optics menu.
Target Blinking	On/Off	By default the fixation target light is on with constant illumination. If patient cannot keep their eye targeted well the light can be changed to blink to help focus on the target light.
Calibration Frequency	(5,10, user)	User can manually set calibration frequency of the optics.

Start Study

This enables the study to start. For every new study, user needs to go into the menu and start study to enable the study or Time counter.

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

IR brightness values are Low/Med/High. This can be chosen by user by using left and right arrow keys. Always high is recommended.

Instant review

Instant review can be ON/OFF according to user need, as available in FA Optics menu.

Target blinking

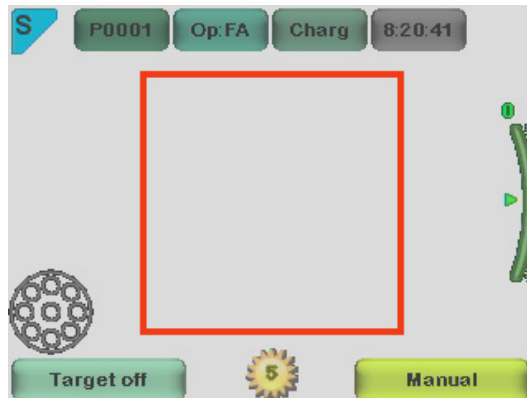
By default the fixation target light is on with constant illumination. If patient cannot keep their eye targeted well the light can be changed to blink to help focus on the target light.

Calibration Frequency

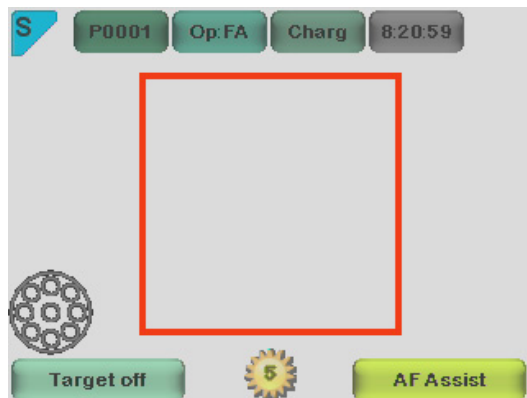
User can manually set calibration frequency of the optics. For Example User selects 5, the device won't calibrate until next five consecutive images taken. Camera stores selected menu settings when it is powered off.

Menu:

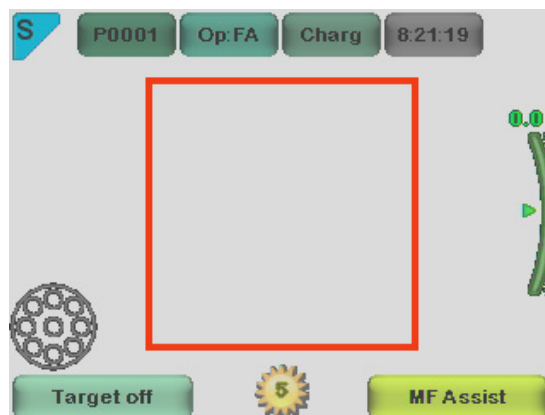
1. Default Display window when FA optics is attached using Manual Mode. You can adjust the Diopter scale according to patient diopter manually. Image can be taken when shutter button held all the way down.
2. op:FA → Optics recognized as FA for fundus angiography imaging.



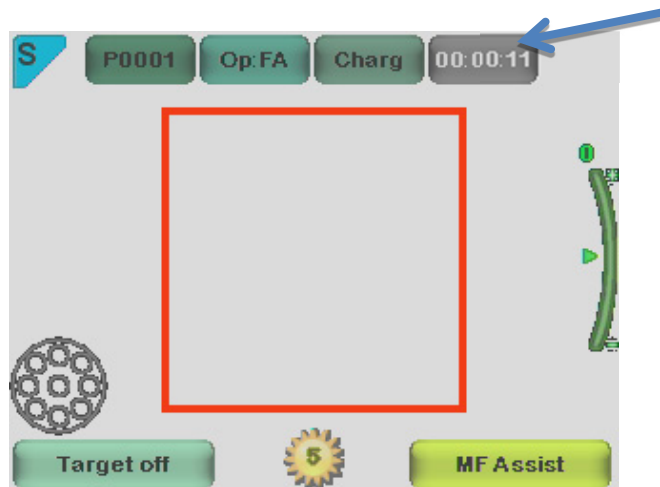
3. Default Display window when FA optics is attached using AF Assist mode. Diopter scale is automatically adjusted, Image can be captured when shutter button is pressed half a way.



4. Default Display window when FA optics is attached using MF Assist mode. Diopter scale is manually adjusted, Image can be captured when shutter button is pressed half a way.



- When Right Arrow key is held down all the way, Menu table appears on display. Default Device tab will be ON. By using left and right arrow keys you slide to the next tab. Here FA tab is chosen.



Time Counter:

Start study is selected from the FA optics menu. After pressing shutter button half way for one time during the live view screen. Time counter will appear on the upper right (pointed with arrow on the image).

Time counter will be printed on the final images.

Time counter will guide you through out through the all phases of Angiography.

To stop the time counter after finishing the study, user need to switch to FA optics menu and press the STOP STUDY button.

TECHNICAL DESCRIPTION

FUNDUS ANGIOGRAPHY MODULE CONNECTED TO THE PICTOR PLUS M5 CAMERA

Type:	Pictor Plus FA
Intended use:	Intended to capture digital images of the fundus angiograms of the human eye.
Illumination:	Infrared LED for targeting Blue LED for photographing, 10 illumination brightness levels 9 red internal fixation target LEDs
Maximum Luminance output level towards eye:	8.07 cd/cm ²
Field of view:	40°
Diopter compensation:	- 20 D to + 20 D
Image resolution:	1536x1152 px (total 1.8 Mpix, informational area 1.41 Mpix)
Dimensions:	160x73mm
Weight:	310 g



ENVIRONMENTAL CONDITIONS FOR USE, STORAGE, AND TRANSPORTATION:

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

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

CONTACT

If you wish to contact your local support personnel please call to: 800-345-8655 or email us at: service@Volk Optical.com

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 failure that the device have.

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 wearing. Any issue related to the stickers attached to the device coming off are not covered by warranty. Repair or service done by non Volk Optical certified service facility is not covered by warranty. For customer support, contact: service@Volk.com

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 Plus 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 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	±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 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	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:

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	3 Vrms	<p>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.</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	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz <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.

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

Manufacturer’s declaration – electromagnetic emissions:

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 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 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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 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
For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			



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 74 77 / 92 70-0
Fax: +49 74 77 / 92 70-70



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

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