

v300H™ Visualization System

Directions for Use



Syris[™]
Scientific



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Table of Contents

TABLE OF CONTENTS	3
INTRODUCTION	4
SAFETY & CLINICAL	4
CONVENTIONS USED / SYMBOLS	4
PATIENT AND USER SAFETY:	6
GENERAL EQUIPMENT SAFETY:	6
GENERAL CAUTIONS	7
ELECTRICAL CAUTIONS	8
FIRE CAUTIONS	8
SETUP & USE OF DEVICE	9
UNPACKING & INSPECTION	9
v300H COMPONENT PARTS	10
WEARING THE DEVICE-ADJUSTING FOR USE	10
HEADBASKET ADJUSTMENT	11
SET-UP OF WIRING SYSTEM AND TURNING ON THE v300H ON/OFF	12
PRODUCT OPERATION	13
ILLUMINATOR REPLACEMENT AND CONDITION INDICATOR	14
HEADBAND REPLACEMENT	15
MAINTENANCE & SUPPORT	16
HANDLING AND STORAGE	16
CLEANING	17
v900L SPECIFICATIONS	18
v900L STANDARDS	18
v900L, PARTS AND ACCESSORIES ORDERING INFORMATION	19
SERVICE AND SUPPORT	19
WARRANTY	20
APPENDIX A IMMUNITY ALL EQUIPMENT AND SYSTEMS	21

Introduction

The v300H Vision Enhancement System combines proprietary halogen illumination, polarization, and magnification technology to enhance the vision of medical professionals during dermatological procedures. The system removes surface glare from the patient's dermal layer promoting improved viewing of sub-surface features.

The polarizer rotates to allow for surface and sub-surface viewing. The adjustable Visi-Shield provides magnification and a clear field of view.

Safety & Clinical

**WARNING:**

The v300H is for vision enhancement use by a qualified medical professional during dermal procedures. Read all Warnings, Cautionary Statements and Directions in their entirety before operating the v300H.

Conventions Used / Symbols






















This manual and device packaging uses internationally accepted conventions in describing information requiring further attention by the user.



WARNINGS: Indicate a hazardous situation which, if not avoided or adequate precautions taken, could result in loss of life or serious injury to the user or patient and potential device damage.



CAUTIONS: Indicate a hazardous situation which, if not avoided or adequate precautions taken, could result in minor or moderate injury to the user or patient, or device damage.

 Caution, consult accompanying documents	 Keep dry
 Manufacturer	Qty Quantity
 Consult instructions for use	 Dispose of accordingly
 Fragile, handle with care	 Allowable humidity range
 Temperature limitation	 Allowable temperature range
 Power on/off	 MRI Unsafe
 IEC 61140 Class II Electrical Appliance	 DO NOT plug AC power supply into Control Box
 Dangerous Voltage!	 Direct Current (DC)
 On	 Alternating Current (AC)
 Off	VDC Volts Direct Current
 CE Conformity	A Amperes
 Consult Operating Instructions	 Symbol for hot surface

Patient and User Safety:**WARNING:**

The v300H is for use by qualified medical personnel only.

General Equipment Safety:**WARNING:**

To avoid the risk of electrical shock, inspect the control box, power supply and cables for damage before use. Do not use the v300H or accessories if damaged.

Use only Syris supplied control box, cables, power supply and accessories. In the event of visible damage, do not use and contact Syris for replacement.

DO NOT use the v300H Control Box/Switch in an oxygen-enriched environment.

DO NOT operate the system in a flammable or explosive atmosphere.

Unplug the Power Supply from the AC main wall outlet to remove main power.

DO NOT position Power Supply where it is difficult to disconnect the Power Supply from the AC main wall outlet.

DO NOT modify the v300H equipment without authorization of Syris Scientific.

DO NOT touch illuminator during use of the v300H.

Ensure the power supply pig tail din connector aligns properly with the Lower DC cable connector to form a proper fit.

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protected earth.

Use only Syris supplied Control Box/ Switch z4093-04, Power Supply z2077-00, cables and accessories. In the event of visible damage, do not use and contact Syris for replacement.

**CAUTIONS:****General Cautions:**

Store the device where it will not be accessible by children or untrained people.

DO NOT drop any component of the system. Physical shock may cause permanent damage.

DO NOT use the system as a light to navigate your environment.

DO NOT operate machinery, equipment or vehicles with the v300H positioned on the head and do not walk or climb stairs while wearing the v300H to avoid a tripping or falling accident.

Turn v300H off before storage.

Clean the v300H between users.

To reduce the potential of cross contamination between users, it is recommended that the v300H be cleaned and /or the disposable headband pads be replaced; and / or sanitary head covering, such as a bouffant be used.

DO NOT sterilize or autoclave the v300H or its accessories using heat, steam or pressure.

Never clean any component of the system with abrasive cleaners or objects.

Use only non-abrasive, lint free materials to clean the device.

DO NOT use ammonia-based cleaners.

DO NOT apply cleaner directly onto device or its components.

The v300H and its accessories are not field-serviceable. Do not attempt to repair or use a malfunctioning unit. Doing so could result in injury and will void the product warranty. Servicing is to be performed only by Syris Scientific or their authorized service centers. Unauthorized servicing voids the warranty.

DO NOT examine eyes, vasculature in the eye, or other structures of the eye.

DO NOT look or have patients look directly into the Illuminator Module.

DO NOT wear the v300H if you experience any strain in the neck, eyes or other areas.

DO NOT use the system without the fan operating and the opening free for air flow.

DO NOT clean when v300H is on.

Electrical Cautions

DO NOT allow any liquids to enter into any connectors or into the Illuminator Module.

DO NOT immerse any component of the v300H (including control box, cables or power supply) in water or other liquids.

Only use an approved, grounded outlet when using the Power Supply.

DO NOT allow metal objects or body parts to touch electrical connections.

DO NOT insert any objects into any opening on the v300H.

Use only Syris supplied Control Box / Switch z4093-04, Power Supply z2077-00, cables and accessories. In the event of visible damage, do not use and contact Syris for replacement.

Fire Cautions

DO NOT block any opening of the system; this may cause overheating of the Illuminator Module.

Avoid operating the system in dusty environments.

Setup & Use of Device

Unpacking & Inspection

Please ensure your v300H Vision Enhancement System includes all of the items listed below. Visually inspect all items for any damage. Contact Syris prior to use if any items are missing or appear to be damaged.

<u>Item</u>	<u>Part #</u>	<u>Qty</u>
1. v300H Headgear	Z4093-00	1
1a. v300H Illuminator	Z4093-07	1
1b. Visi Shield	Z2075-00	1
2. Upper DC Power Cable	Z1762-00	1
3. Control Box/Switch	Z4093-04	1
4. Lower DC Power Cable	Z2079-00	1
5. Power Supply	Z2077-00	1
6. AC Power Cord *		
*1 AC Power Cord included	Z2077-UK	1
7. Carrying Case	Z1770-00	1
8. V300H DFU-Directions for Use	v300H-DFU	1



Figure: 1 v300H and Components

v300H Component Parts:

Figure: 2 v300H Component Parts

**WARNING:**

To avoid the risk of electrical shock, inspect the control box, power supply and cables for damage before use. Do not use the v300H or accessories if damaged.

Use only Syris supplied Control Box/Switch z4093-04, Power Supply z2077-00, cables and accessories. In the event of visible damage, do not use and contact Syris for replacement.

Wearing the Device-Adjusting for Use

CAUTION: To reduce the potential of cross contamination between users, it is recommended that the v300H be cleaned and /or the disposable headband pads be replaced; and / or sanitary head covering, such as a bouffant be used.



DO NOT wear the v300H if you experience any strain in the neck, eyes or other areas.

Place the v300H on the user's head to check for fit. The head basket is adjusted by adjusting the head basket strap and rear adjustment knob.

Head basket Adjustment

1. Begin by adjusting the height of the top strap of the head basket. This strap is adjusted by separating the strap and sliding it to a new position. The strap is secured by locking the plastic button on the lower strap into the holes of the upper strap. It is critical that the top strap of the head basket be adjusted to allow the rear section of the head basket to fit below the occipital lobe. See *Figure 3*
2. Loosen the head basket by pushing in the outer ring surrounding the rear knob at the back of the head basket and turn it counter-clockwise.
3. Position the head basket on your head, ensuring that the front of the headband sits comfortably above your eyebrows and the rear of the head basket at the base of the occipital lobe. This system will be uncomfortable and top heavy without this adjustment. If the head basket sits too high or too low on your head, repeat step one.
4. Tighten the head basket by pushing in the outer ring surrounding the rear knob and turn it clockwise until it fits securely.
5. Adjust the position of the Visi-Shield by turning the knobs on both sides of the head basket, counter clockwise to loosen and clockwise to tighten. When properly positioned, the magnifying lens should be in your normal line of sight. See *Figure 4*



Figure 3: Head basket strap



Figure 4: Visi-Shield Knobs

Set-Up of Wiring System and Turning the v300H On/Off



CAUTION: DO NOT look or have patients look directly into the Illuminator Module.

Plug the “straight end” of the Upper DC Cable into the back of the Illuminator Module. Place the cord under the “Syris” velcro strip located at the rear of the headband to keep it in place.

Plug the phone plug angled end of the Upper DC Cable into the “output” section located on the top of the Control Box/Switch.

Plug the angled end of the Lower DC Cable into either side of the Control Box/Switch.

Plug the female end of the DIN connector of the Lower DC Cable into the male DIN pigtail connector of the Power Supply. Line up male pins to female connector and avoid twisting that will cause damage.

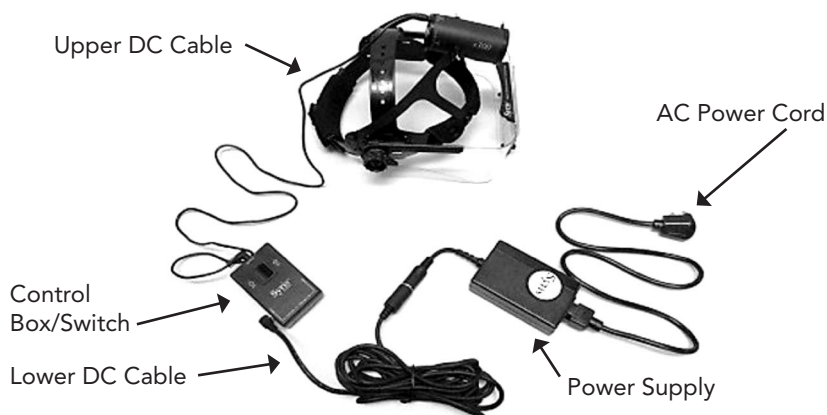


Figure: 5 v300H Wiring System

Plug the Medical AC power input cord into the Power Supply Module. Make sure it is a tight fit by pushing twice.

Plug the prong end of the power cord into the wall outlet.

After completing the wiring setup procedure, place it on your head, adjust the position of the illuminator for your subject and then turn the switch of the Control Box/Switch to on.

To prevent shock to the Illuminator Module, the system is designed to gradually turn on the Illuminator over a five second period.

To turn off the v300H Vision System, disconnect the AC Power Input Cable from the wall outlet.

The plug of the specified power supply cord serves as the disconnect device.

Important: To prevent shock to the Illuminator Module, the system is designed to gradually turn on the Illuminator over a five second period.

Important: If there is no evidence of the light when you turn the system on, immediately turn off using the Control Box / Switch. Check the wiring setup again.

Important: To avoid creating fractures in the Lower DC cable and pigtail of the Power Supply, do not wrap the Lower DC Cable around the Power Supply.

Product Operation



WARNING: DO NOT touch illuminator of the V300H during operation.

The v300H Visualization System is intended to enhance the vision of medical professionals when used in the patient environment during inspections and procedures.

The v300H Visualization System is designed to enhance the surface or the sub-surface features of a patient's skin. This is accomplished by parallel-polarizing or cross-polarizing the light emitted from the Illuminator Module. To change between surface and sub-surface viewing mode, use the following simple procedure:

1. While wearing the Headgear and before turning it on, locate the Illuminator Module with your free hand.
2. Slide your hand down the Illuminator Module until you locate the adjustment peg located at the front of the barrel.
3. Gently grasp the adjustment peg and rotate it as shown in *Figure 6*.
4. As worn on the head, the surface (parallel-polarized) mode will be seen when the adjustment pin is at the 12 O'clock position. The sub-surface (crossed-polarized) mode will be seen when the adjustment peg is at the 3 O'clock position.
5. When you have adjusted the illuminator to the desired position on your subject you can then turn on the device using the Control Box/Switch.

NOTE: In order to observe the effects of the system, the user must look through blue polarized section of the Visi-Shield.

Sub-Surface view-
12 o'clock position



Surface view -
3 o'clock position

Adjustment peg

Figure 6: v300H Sub-Surface / Surface Adjustments

Illuminator Replacement

As with any intense illumination source, the v300H Illuminator Module will wear out with use. Exacting tolerances and high output cooling of the Illuminator Module extends the expected life to 400+ hours under normal conditions.

Please use the following procedures to replace the Illuminator Module in your v300H Visualization System. If you have any questions, please contact our customer service at 800.714.1374 (within US) or 207.657.7050.

Illumination Condition Indicator

The v300H Series is equipped with one of the most sophisticated diagnostic systems of any lighting or vision system in the medical world. A powerful microprocessor constantly monitors the entire system of the lighting and cooling to ensure maximum performance. Part of this computer's function set is a display of the *Illuminator Module's* condition. Three colored LED's are installed to be visible through the air outlet vents on the rear of the illuminator.

Green: Will remain visible for the first 75% of its life expectancy.

Yellow: Will indicate 5-24% of life expectancy remains. It is suggested to order replacement at this point.

Red: Will indicate less than 5% of life expectancy remains. The bulb will alternate dim and bright 7 times at startup during this critical stage showing that the illuminator module has reached its life expectancy.

The LED's flash a readout of the elapsed hours on the Illuminator Module 30 seconds after the power is applied. The red LED flashes the number of hundreds of hours, the yellow flashes the number of 10s of hours and the green flashes

the number of single hours, so 124 hours would be 1 red, 2 yellow and 4 green. This is followed in another 15 seconds by a second series of flashes showing the number of on/off cycles. This sequence differs from the first in that it is divided by 10, so 120 would be 1 yellow and 2 green flashes.

A typical life span for an Illuminator Module is in excess of 400 hours. Should your illuminator fail prior to 400 hours, a pro-rated warranty will apply.

v300H Illuminator Module Replacement

1. Turn off the v300H Visualization System and disconnect the AC Power Input Cable from the wall outlet. Disconnect the Upper DC Power Cable from the old Illuminator Module.
2. Allow illuminator to cool at least 5 Minutes before proceeding.
3. Loosen the plastic wing nuts on either side of the old Illuminator Module approximately one turn, and remove it from the Headgear frame.
4. Install the new Illuminator Module on the Headgear frame and tighten the plastic wing nuts.
5. Connect the Upper DC Power Cable to the Illuminator Module, and plug AC Power Input Cable into a wall outlet.
6. Turn the system on and make sure the both the lamp and fan are functioning.

Headband Replacement



CAUTIONS:

To reduce the potential of cross contamination between users, it is recommended that the v300H be cleaned and /or the disposable headband pads be replaced; and / or sanitary head covering, such as a bouffant be used.

The Headband Pads may be cleaned or replaced as desired. **To maintain the comfort level designed into the v300H and for sanitary purposes, it is recommended that the Headband Pads be replaced monthly.** Purchase additional Headband Pads (v300H-80) through Syris Scientific.



Figure 7: Headband Pad locations

Maintenance & Support

The v300H does not require any periodic maintenance other than routine cleaning. There are no user serviceable components within the device. To obtain additional comfort Headband Pad sets, replacement parts or service, call Syris Scientific at 207-657-7050, Monday-Friday, 8:00 a.m. to 5:00 p.m. EST or visit the website www.syrisscientific.com.

Handling and Storage



CAUTION: Store the device where it will not be accessible by children or untrained people.

Turn v300H off before storage.

Use carrying case to move the v300H an extended distance.

- To protect the system, store in the carrying case provided with unit.
- For short term storage, the Power Supply may remain plugged in, but the Power Control Box/Switch should be turned off.
- For long term storage, Power Supply should be unplugged.

NOTE: When returning the unit into the case, release side knobs on head basket so unit is in flat position. Position illuminator to a horizontal position and the polarizer pin is to one side.

Operate at 32°F to 90°F [0°C to 32°C] and 0-80% relative humidity.

Store Between -4 °F and 122 °F [-20°C and 50°C] and 0-95% relative humidity.

Cleaning



CAUTIONS:

Clean the v300H between users.

DO NOT immerse any component of the v300H (including control box, cables or power supply) in water or other liquids.

DO NOT sterilize or autoclave the v300H or its accessories.

DO NOT apply cleaner directly onto device or its components.

DO NOT use ammonia based cleaners.

Use only non-abrasive, lint free materials to clean the device.

Never clean any component of the system with abrasive cleaners or objects.

DO NOT sterilize the v300H or its accessories using heat, steam or pressure.

DO NOT allow any liquids to enter into any connectors or into the Illuminator Module.

DO NOT clean when v300H unit is on.

The v300H head basket can be wiped down using any common non- abrasive chlorine or alcohol based cleaners found in a medical environment.

The v300H is an optical instrument and the optical surfaces need to be kept clean for optimum image quality.

Clean the Visi-Shield and magnifying lenses with a lint-free lens cloth dampened with an alcohol-base, non-abrasive cleanser typically used for cleaning glasses.

v300H Specifications

Headset weight	<12 oz.
Approx. system ship weight	6 pounds
Working distance with #3 Lens	14 inches
with #4 Lens	10 inches
with #5 Lens	8 inches
Power Supply Input Output	Input: 100-250 VAC, 50-60HZ Output: 13.8 VDC, 3A maximum
Illuminated Viewing Area	6-8 inches
Power Source	AC 110-240V
Min/Max operating temperature	32°F / 90°F (0°C / 32°C)
Min/Max storage temperature	-4°F / 122°F (-20°C / 50°C)
Humidity Storage	0-95% RH
Humidity Operating	0-80% RH

v300H Standards

IEC 60601-1	Medical Electrical Equipment Performance and Safety (3rd edition)
IEC 60601-1-1:	Medical Electrical Equipment Safety
IEC 60601-1-2:	Medical Electrical Equipment Electromagnetic Compatibility
ANSI/AAMI	American National Standards Institute Association for the Advancement of Medical Instrumentation
CSA	Canadian Standards Association

v300H, Parts and Accessories Ordering Information

z4093-00	v300H Vision Enhancement System
z4093-07	v300H Illuminator
z1762-00	Upper Cable
z2096-00	Visi-Shield #4 Lens
z2098-00	Visi-Shield #5 Lens
z4093-04	Control Box/Switch
z2077-00	Power Supply
z2383-00	Headband Pads
v300H-DFU	Directions For Use

Note: Manuals are available in English, French, German, Italian, and Spanish, by downloading from www.syrisscientific.com.



WARNING:

Use only Syris supplied control box, cables, power supply and accessories. In the event of visible damage, do not use and contact Syris for replacement.

Use only Syris supplied Control Box/ Switch z4093-04, Power Supply z2077-00, cables and accessories. In the event of visible damage, do not use and contact Syris for replacement.

Service and Support



CAUTION: The v300H and its accessories are not field-serviceable. Do not attempt to repair or use a malfunctioning unit. Doing so could result in injury and will void the product warranty. Servicing is to be performed only by Syris Scientific or their authorized service centers. Unauthorized servicing voids the warranty.

For Assistance Contact Syris Scientific:

Customer and Technical Support within the U.S. and Canada:

Monday-Friday, 8:00 a.m. to 5:00 p.m. EST

Telephone: **207.657.7050** / Facsimile: **207.657.7051**

Email: info@syrisscientific.com

Warranty

Syris Scientific (Syris) warrants that the Equipment conforms to any specifications provided in writing by Syris to Customer for that Equipment, is of sound materials and workmanship, is new and unused, unless otherwise specified.

Standard Warranty

Standard Warranty Period. The Warranties with respect to any Equipment shall remain in effect for the following period of time after delivery of the Equipment to the Customer (the "Warranty Period"): (1) One year for the v300H.

1. Notice of Warranty Claim. If at any time during the applicable Warranty Period, the Customer believes that the Equipment does not comply with any of the Warranties, the Customer shall promptly notify Syris of a Warranty Claim. If the Customer does not provide notice of Warranty Claim within the Warranty Period, the Customer shall not have any right to claim that the Equipment does not comply with the Warranties. The Customer shall inspect the Equipment promptly after delivery to the Customer and promptly notify Syris of any alleged breach of any Warranties or any errors relating to the delivery of the Equipment.

2. Repairs and Replacements. If within the applicable Warranty Period the Customer notifies Syris Scientific that any Equipment does not comply with any of the Warranties and if in fact the Equipment does not comply with any of the Warranties (not caused by misuse or abuse), Syris Scientific shall, at Syris Scientific's election and expense, either repair or replace the Equipment. The Customer shall not return any Equipment to Syris Scientific without first obtaining a return authorization number from Syris Scientific or Syris Scientific's authorized distributor. If Customer fails to follow all of Syris Scientific return instructions, including the packaging of the Equipment, the repair will not be covered by this Warranty.

For warranty registration or return of product procedure visit our website at www.syrisscientific.com.

Appendix A Immunity All Equipment and Systems

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV I/Os	±1kV Mains ±1kV I/Os (see justification)	
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the v300H power supply requires continued operation during power mains interruptions, it is recommended that the power supply be powered from an uninterruptible power supply.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Emissions Equipment and Systems that are NOT Life-supporting.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF EN/IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)Vrms	Portable and mobile communications equipment should be separated from the v300H by no less than the distances calculated/listed below: $D = (3.5/V1)(\text{Sqrt } P)$
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)V/m	$D = (3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz $D = (7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances between portable and mobile RF Communications Equipment and the v300H Equipment and Systems that are NOT Life-supporting. Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $D = (3.5/V1)(\text{Sqrt } P)$	Separation (m) 80 to 800MHz $D = (3.5/E1)(\text{Sqrt } P)$	Separation (m) 800MHz to 2.5GHz $D = (7/E1)(\text{Sqrt } P)$
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Guidance and manufacturer's declaration – electromagnetic emissions

The v300H is intended for use in the electromagnetic environment specified below. The customer or the user of the v300H should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The v300H 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 A	The v300H is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
		Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the v300H or shielding the location.



WARNING

The v300H is intended for use in the electromagnetic environment in which radiated disturbances is controlled.

The customer or user of the v300H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the v300H as recommended below, according to the maximum output power of the communications equipment.

Other cables and accessories may also negatively affect EMC performance and result in non-compliance.

The v300H should not be used adjacent to other equipment and that if adjacent or stacked use is necessary, the v300H should be observed to verify normal operation in the configuration in which it will be used.

NOTES

Thank you for purchasing Syris Products!

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Syris Doc # 9003 R02