

v900L™ Visualization System

Directions for Use

v900L-DFU Doc #9001_1



Syris[™]
Scientific



Syris Scientific, LLC.

22 Shaker Rd.,

P.O. Box 127, Gray, Maine, USA 04039

Phone: 207.657.7050

Fax: 207.657.7051

Email: techsupport@syrisscientific.com

Web: www.syrisscientific.com

Service Center Hours: Monday – Friday

8:00AM – 5:00PM US Eastern Time



CEPartner4U BV

Esdoornlaan 13,

3951DB Maarn

The Netherlands

www.cepartner4u.eu

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Introduction

The v900L Vision Enhancement System combines proprietary LED 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.

Powered by a lithium ion battery, the system provides mobility for the user. 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 v900L 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 v900L.

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 module

Patient and User Safety



WARNINGS:

The v900L is for use by qualified medical personnel only.

General Equipment Safety



WARNINGS:

To avoid the risk of electrical shock, inspect the battery charger cable and plug for damage before use. Do not use the v900L or accessories if damaged.

Use only Syris supplied battery charger, control box, cable, battery, and accessories. In the event of visible damage, do not use and contact Syris for replacement. VTS1000 Power Supply is a part of the v900L system and should only be used with battery Charger Base VTS1000-Charger.

DO NOT use the Charger Base, or insert or remove the Syris battery from the v900L Control Module in an oxygen enriched environment.

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

Unplug the VTS1000-PS Power Supply from the AC main wall outlet to remove main power.

DO NOT position VTS1000-Power Supply and VTS1000-Charger Base where it is difficult to disconnect the Power Supply from the AC main wall outlet.

DO NOT modify the v900L equipment without authorization of the Syris Scientific.

DO NOT plug power supply L-shaped connector into Control Module.



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 v900L positioned on the head and do not walk or climb stairs while wearing the v900L to avoid a tripping or falling accident.

Turn v900L off before storage.

Remove battery from v900L Control Module when not used for an extended period of time.

To reduce the potential of cross contamination between users, it is recommended that the v900L be cleaned and/or the disposable headband pads be replaced; and/or sanitary head covering, such as a bouffant be used.

Clean the v900L between users.

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

DO NOT use ammonia based cleaners.

DO NOT immerse any component of the v900L (including battery charger, control box, cable or batteries) in water or other liquids.

DO NOT sterilize or autoclave the v900L or its accessories.

Dispose of batteries and accessories per your facility policy or local regulations.

The v900L 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 v900L if you experience any strain in the neck, eyes or other areas.

Electrical Cautions

Never immerse any component of the system in any liquids.

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

Only use an approved, grounded outlet to charge the battery.

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

DO NOT insert any objects into any opening on the v900L.

Only use provided power supply, Control Module and cable with this system.

DO NOT touch the battery contact of the VTS1000 Battery and the patient at the same time.

Fire Cautions

DO NOT block any opening of the system. Doing so may cause overheating of the Illuminator Module.

Avoid operating the system in dusty environments.

Setup & Use of Device

Unpacking & Inspection

Please ensure your v900L 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. v900L, Vision Enhancement System	v900L-00	1
2. Control Module	v900L-70	1
3. Battery	VTS1000-BAT	1
4. Battery Charger System *	VTS1000-CHARGER	1
5. Carrying Case		1
Control Module Belt **		1
Carrying Case Strap **		1
6. Directions For Use (DFU) ***	v900L-DFU	1
	v900L-DFU-Intl	1

* Includes charger base and power supply

** Included in carrying case

*** One DFU included



v900L Component Parts:

Figure 1: v900L, Illuminator, and Visi-Shield

**WARNING:**

To avoid the risk of electrical shock, inspect the battery charger cable and plug for damage before use. Do not use the v900L or accessories if damaged.

Use only Syris supplied battery charger, control box, cable, battery, and accessories. In the event of visible damage, do not use and contact Syris for replacement. VTS1000 Power Supply is a part of the v900L system and should only be used with battery Charger Base VTS1000-Charger.

Charging the Battery Using Charger Base/Power Supply



WARNING: DO NOT use the Charger Base, or insert or remove the Syris battery from the v900L Control Module in an oxygen enriched environment.



WARNING: Unplug the VTS1000 Power Supply from the AC main wall outlet to remove main power.



WARNING: DO NOT position VTS1000-Power Supply and VTS1000-Charger Base where it is difficult to disconnect the Power Supply from the AC main wall outlet.

Fully charge the battery before initial use of the v900L. A fully charged battery will provide approximately 4 hours of continuous use.

Batteries are shipped in a partially charged state.

Select appropriate AC adapter and ensure that the AC adapter snaps securely into Power Supply. Prior to initial use, plug the power supply into an approved 100-240 VAC, 50/60Hz wall outlet. Insert battery into Charger Base and the indicator light begins to blink green indicating that charging has begun. Charging is complete when the indicator light on the charger base unit turns solid green, approximately five hours for initial full charge.





To avoid downtime, it is recommended that a second battery (VTS1000-BAT) be acquired to allow the use of the v900L while the depleted battery is being charged.



Figure 2: Charger Base and Battery

Indicator Light

Charger indicator lights can have four possible states as follows:

- | | | | |
|--|---|--|---------------|
|  Solid Red | No battery detected |  Blinking Green | Charging |
|  Blinking Red | Fault condition, battery or charger defective |  Solid Green | Fully charged |

Installing/Removing Battery from the Control Module



CAUTION: Do not use batteries if visibly damaged or the Charger Base indicates a faulty battery.



WARNING: Do not use the Charger Base, or insert or remove the Syris battery from the v900L Control Module in an oxygen enriched environment.

Install the Battery into the Control Module by inserting the battery tabs at the bottom of the battery into the battery tab pockets of the Control Module. Press down the blue tab on the top of the Battery and pivot the battery into the Control Module. Release the blue tab making sure the Battery securely locks into place. See Figure 3.

To remove the Battery, press down the blue tab and pivot the Battery out of the Control Module.

Note: After inserting Battery into Control Module, attach Control Module onto belt. Make sure belt is secure on the body before inserting the L-shaped plug of the Illuminator Cable into the Control Module as shown in Figure 3.



Figure 3: Control Module and Battery

Control Module Indicator Lights and States



WARNING: DO NOT plug power supply L-shaped into connector into Control Module.



Power on/off

Depressing the blue on/off button on the Control Module once provides full power. Depressing it a second time reduces the light intensity. Depressing it a third time shuts off the power. See figure 3 on page 12.

- Green – Over 30* minutes of operation time at full power remain.
- Orange – Less than 30* minutes of operation time at full power remain.
- Red – Less than 10* minutes of operation time at full power remain.

When the battery indicator is red the unit will emit 3 tones every 30 seconds until the unit automatically shuts down.

*Time is typical

Reducing the light intensity to the low setting will extend the operation time by approximately 33%.

Wearing the Device-Adjusting for Use



CAUTION: To reduce the potential of cross contamination between users, it is recommended that the v900L be cleaned and/or the disposable headband pads be replaced; and/or sanitary head covering, such as a bouffant be used.

After placing the v900L device on the user's head, the head basket is adjusted by turning the adjustment knobs. See Figure 4.

Upper adjustment knob: Turn clockwise to raise and counter-clockwise to lower.

Back adjustment knob: Turn clockwise to tighten and counter-clockwise to loosen.



Figure 4: Head basket adjustments

1. 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.
2. Position the v900L on your head, ensuring that the front of the headband sits comfortably above your eyebrows and the rear of the headband sits at the base of the occipital lobe. If the head basket sits too high or too low on your head, repeat step 1.
3. Adjust the position of the Visi-Shield by gently raising and lowering the support arm, using forefinger and thumb, up or down and the Visi-Shield in or out. When properly positioned, the magnifying lens should be in your normal line of sight. See Figure 5 on page 15.

Note:

1. The Visi-Shield support arm raises and lowers with the finger and thumb.
2. The Visi-Shield pivots toward or away from the user.
3. The Illuminator Module lifts up and down.
4. The Adjustable Polarizer slides from left to right



Figure 5: Illuminator and Visi-Shield adjustments.

Turning the v900L On/Off and Adjustments



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

With a charged battery installed in the Control Module and the illuminator cable connected to the Control Module, press the blue power button once to turn the v900L on with its brightest light. An audible beep and a green LED will indicate the unit is on. Push the button a second time to reduce light intensity, indicated by an audible beep and the green LED will remain on. Press the button a third time to turn the unit off, indicated by another audible beep and the green LED off.

Headband Replacement

The Headband Pads may be cleaned or replaced as desired. **To maintain the comfort level designed into the v900L and for sanitary purposes, it is recommended that the comfort Headband pads be replaced monthly.** Purchase additional Headband Pads (v900L-80) through Syris Scientific.



Figure 6: Headband Pad locations

Maintenance & Support

The v900L does not require any periodic maintenance other than routine cleaning. There are no user serviceable components within the device. To obtain additional batteries, 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.

When not in use, power off the v900L to preserve battery life.

Use carrying case to move the v900L an extended distance.

Remove Battery from v900L Control Module when not used for an extended period of time.

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

Clean the v900L between users.

DO NOT apply cleaner directly onto device or its components.

DO NOT use any product containing ammonia.

The v900L head basket can be wiped down using any common non-abrasive chlorine or alcohol based cleaners found in a medical environment.

The v900L is an optical instrument and the optical surfaces need to be kept clean for optimum image quality.

It is recommended to clean the Visi-Shield with a lens cloth dampened with an alcohol-based non-abrasive cleanser typically used for cleaning glasses.

The Visi-Shield and magnifying lenses should be wiped with an optical cloth or equivalent non-abrasive, lint free cloth.

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

**CAUTIONS:**

DO NOT immerse any component of the v900L (including battery charger, control box, cable or batteries) in water or other liquids.

DO NOT sterilize or autoclave the v900L or its accessories.

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

v900L Specifications

Headset weight	<13 oz.
Approx. system ship weight	< 5 pounds
Working distance with #3 Lens	14 inches
with #4 Lens	10 inches
with #5 Lens	8 inches
Illumination wavelength	400-700 nanometers
Battery type	Sealed 7.4V lithium ion
Battery run time	240 minutes (4 hours) typical
Battery charge time	300 minutes (5 hours) typical
Exposed materials	Brass, Cellulose Triacetate, Glass, Gold, Nickel, Phosphor Bronze, Stainless Steel
Battery charger input voltage	100-240 VAC, 50/60 Hz
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

v900L Standards

IEC 60601-1	Medical Electrical Equipment Performance and Safety (3 rd 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
UN/DOT 38.3	Transport of Lithium Batteries

v900L, Parts and Accessories Ordering Information

v900L-00	v900L Vision Enhancement System
v900L-10	Illuminator
v900L-20	Upper Cable
v900L-30	Visi-Shield #3 Lens
v900L-40	Visi-Shield #4 Lens
v900L-50	Visi-Shield #5 Lens
v900L-70	Control Module
v900L-80	Replacement Comfort Headbands, (10 sets)
VTS1000-BAT	Battery, Additional
VTS1000-CHARGER	Battery Charger Base/Power Supply
v900L-DFU	Directions For Use
v900L-DFU-Intl	Directions For Use (International)

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

**WARNING:**

Use only Syris supplied battery charger, control box, cable, battery, and accessories. In the event of visible damage, do not use and contact Syris for replacement. VTS1000 Power Supply is a part of the v900L system and should only be used with battery Charger Base VTS1000-Charger.

Service and Support



CAUTION: The v900L 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.

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

- 1. 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 v900L; and (2) Ninety (90) days for any v900L battery.
- 2. 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.
- 3. 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 v900L VTS-1000 charging system requires continued operation during power mains interruptions, it is recommended that the charger be powered from an uninterruptible power supply or battery.
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 v900L by no less than the distances calculated/listed below: $D=(3.5/V1)(\text{Sqrt } P)$ $D=(3.5/E1)(\text{Sqrt } P)$ $D=(7/E1)(\text{Sqrt } P)$ 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.
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)V/m	

Recommended Separation Distances between portable and mobile RF Communications Equipment and the v900L 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 v900L is intended for use in the electromagnetic environment specified below. The customer or the user of the v900L should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The v900L 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 v900L 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: 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 v900L or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	



The v900L is intended for use in the electromagnetic environment in which radiated disturbances are controlled.

The customer or user of the v900L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the v900L 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 v900L should not be used adjacent to other equipment and that if adjacent or stacked use is necessary, the v900L should be observed to verify normal operation in the configuration in which it will be used.

NOTES

Thank you for purchasing Syris Products!

Syris Scientific, LLC

22 Shaker Rd.
P.O. Box 127
Gray, Maine 04039
207.657.7050 TEL
207.657.7051 FAX

WWW.SYRISSCIENTIFIC.COM

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