



LED DayLite[®] HDi[™]

SURGICAL

USER GUIDE

Model: DVI-LEDSC

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DESIGNS FOR VISION, INC. LED DAYLITE® HDI™

The Designs for Vision LED DayLite® HDi™ Headlights provide bright, portable light to the surgical environment. They are designed to be comfortable yet functional. The headlights are made to clip onto a wide variety of frames and/or headsets.

INDICATIONS FOR USE

The Designs for Vision LED DayLite® HDi™ is an illumination device and video recording device (if equipped) used to aid in visualization for medical professionals. It is intended to illuminate and document (if equipped) various tissues and/or body parts. This device is intended to be used by medical professionals, requiring no specific training other than what is contained in this manual.

CONTRAINDICATIONS

None known

WARNINGS



Save these instructions. This manual contains important safety and operating instructions



Always examine the unit and accessories for damage before commencing use. Damaged accessories must not be used and must be replaced. Use original Designs for Vision, Inc. parts and accessories only. The use of unapproved parts may void the warranty.

To reduce the risk of battery explosion, follow these instructions and those marked on the battery

Do not Autoclave

For indoor use only

If the equipment is used in a manner not specified by Designs for Vision, Inc., the protection provided by the equipment may be impaired

A spent battery should not be used. Contact Designs for Vision Inc. for ordering a replacement

Replace with Designs for Vision, Inc. battery only. Using unapproved batteries may not work and will void the warranty



This equipment and accessories do not contain serviceable parts. All repairs need to be conducted by Designs for Vision, Inc. service personnel

Do not let liquids enter openings or ports. Do not immerse parts in solutions. Allowing liquids to enter openings or ports may void warranty.

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or in an oxygen rich environment

Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device

No modification of this equipment is allowed. Performing unauthorized modification on the equipment, accessories or the product labelling may void the warranty

Remove battery from power pack if this device

is not in use and will be stored for some time. Maintain storage at environmental conditions listed below



Improper use of battery may cause them to get hot, ignite or explode. Always follow all safety precautions listed in this manual

Never make changes or modifications to the battery pack

Do not short circuit

Do not expose to fire

When replacing battery, be careful to not crimp or crush wires inside of power pack

Protect battery from fluids and damp environments

Charge batteries with supplied charger only




Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately, and must be disposed as per local regulations

SPECIFICATIONS

<p>POWER REQUIREMENTS Designs for Vision, Inc.® LED DayLite® HDi™ Model Number: DVI-LEDSC</p> <p>A) Cell-Con Charger Model P/N: 2240</p>	<p>Battery Power : 7.4VDC, 3400mAh 18650 Li-Ion Battery</p> <p>For Charging : Input : 100-240VAC, 50/60 Hz, 1.0A Output : 7.4 VDC, 1.0A max</p> <p>USB Power (NanoCam HD™) : Input : 5VDC, 0.18A</p>
<p>ILLUMINATION At 12" measured with a cosine corrected light meter UltraMini®/UltraMini® HDi™: NanoCam HDi™:</p> <p>At 13" measured with a cosine corrected light meter USB DayLite®/DayLite® HDi™:</p> <p>At 16" measured with a cosine corrected light meter TwinBeam®/TwinBeam® HDi™: TwinBeam® IR HDi™:</p>	<p>0 – 55,000 lux ± 10% 0 – 29,000 lux ± 7%</p> <p>0 – 100,000 lux ± 7%</p> <p>0 – 140,000 lux ± 7% 0 – 140,000 lux ± 7%</p>
<p>TRANSPORT & STORAGE TEMPERATURE: RELATIVE HUMIDITY: ATMOSPHERIC PRESSURE:</p>	<p>-40°C to 70°C 10% to 100% including condensation 500 to 1060 hPa</p>

ENVIRONMENTAL OPERATING CONDITIONS	
TEMPERATURE:	10°C to 40°C
RELATIVE HUMIDITY:	30% to 75%
ATMOSPHERIC PRESSURE:	700 to 1060 hPa
OVERCURRENT PROTECTION	Firmware Controlled Protection
RECOMMENDED SYSTEM REQUIREMENTS (NanoCam HD™):	
Operating System:	Windows 7 or better
Available Memory:	2GB <i>Preferred</i>
Available HD Space:	20GB <i>Preferred</i>
Minimum CPU Speed:	1.7GHz <i>or Better</i>
Available USB Ports:	2 Hi-Speed USB2.0
DIMENSIONS	
POWER PACK:	3.60" x 1.95" x .95"
WEIGHT:	4.9 oz.
USB DayLite® HEADLIGHT:	1.15" Dia. x 1.53"
WEIGHT:	.95 oz.
DayLite® HDi™ HEADLIGHT:	1.15" Dia. x 1.76"
WEIGHT:	1 oz.
UltraMini® HEADLIGHT:	.75" Dia. x 1.24"
WEIGHT:	.47 oz.
UltraMini® HDi™ HEADLIGHT:	.78" Dia. x 1.27"
WEIGHT:	.50 oz.
TwinBeam® HEADLIGHT:	11.00" x 7.50" x 6.00"
WEIGHT:	15.2 oz.
TwinBeam® HDi™ HEADLIGHT:	2.62" x 1.56" x 1.62"
WEIGHT:	2.9 oz.
TwinBeam® IR HDi™ HEADLIGHT:	2.62" x 1.56" x 1.62"
WEIGHT:	2.9 oz.

B) NanoCam HD:	1.40" x 1.10" x .90"
B) WEIGHT:	.50 oz.
B) NanoCam HDi™:	1.40" x 1.10" x 1.68"
B) WEIGHT:	1.15 oz.
APPROVALS:	IEC 60601-1, IEC 60601-1-2, Class A, CISPR 11, IEC 62133, IEC 62366-1
EQUIPMENT CLASS:	 Class II
INGRESS OF WATER:	IPX0 (ordinary equipment)
FOOT PEDAL <i>ONLY</i> :	IPX1
MODE OF OPERATION	Continuous
PROTECTION FROM SHOCK:	NO APPLIED PARTS
METHODS OF STERILIZATION	Not Intended to be Sterilized
OXYGEN RICH ENVIRONMENT	Not Intended for Oxygen Rich Environments
PATENTS:	8,851,709; 8,215,791; 7,690,806 HDi™ Technology Patent Pending

A) External charger provided with an approved detachable power supply cord which can be easily and safely remove from supply mains

B) Dimensions and weight measured without the micro-video lens or locking ring

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DEVICE DESCRIPTION

The USB DayLite®/DayLite® HDi™ generates a 2¼” spot of light at a 13-inch working distance with an intensity of 100,000 lux and up to 9-hour battery runtime. The UltraMini®/UltraMini® HDi™ generates a 3” spot of light at a 12-inch working distance with an intensity of 55,000 lux and up to 19-hour battery runtime. Both lights have a correlated color temperature of 5800K.

The TwinBeam®/IR HDi™ generates a 2¾” spot of light at a 16-inch working distance. The light has a correlated color temperature of 5800°K at an intensity of up to 140,000 lux. The unit can run on each battery pack for up to 4.5 hours (power linked to 9hrs) before needing to be recharged.

The NanoCam HD™ records high resolution 1080p video over USB. The attached headlight is designed to provide even color corrected illumination to enhance the images captured. The light has a correlated color temperature of 5800°K at an intensity of up to 22,000 lux. The unit can run on battery power for up to 12 hours before needing to be recharged.

The LED DayLite® HDi™ includes these main components:

- Power Pack(s)
- Desktop Charger w/Power Cord
- UltraMini® Headlight, or
- UltraMini® HDi™ Headlight, or
- USB DayLite® Headlight, or
- DayLite® HDi™ Headlight, or
- USB TwinBeam® Headlight, or
- TwinBeam® HDi™ Headlight, or
- TwinBeam® IR HDi™ Headlight, or
- NanoCam HD™ Camera and HDi™ Headlight
- Headlight Cable

Accessories include:

- Two Holsters w/Belt Clips
- Power Link Cable
- Hex Drivers
- Cable Wrap Kit
- Operation Manual
- Registration Card
- T-Mount Bracket *(sold separately)*
- Headset *(sold separately)*
- Carrying Case *(if equipped)*
- USB Extension Cables *(if equipped)*
- 2.5x/3.5x/WA μ Video Lens System *(if equipped)*
- USB Foot Pedal *(if equipped)*
- USB Drive w/Camera Software *(if equipped)*
- Focusing Card *(if equipped)*

DIRECTIONS FOR USE

LED DAYLITE® HDI™ INITIAL SETUP AND CHARGING

Remove the components from the shipping container, checking that all parts on the packing list have been received. Carefully remove the headlight, power pack(s), desktop charger and charger cord from the packaging carton.

NOTE: The batteries need to receive a full charge before initial operation

The desktop charger is designed to meet multi-national regulatory requirements and has multi-input voltage capability to accommodate various line voltages from 100-

FIG. 1



240 VAC. The unit is to be charged with the supplied charger only. Plug the cord into the jack connector on the front of the power pack (Fig. 1).

Plug the power cord into the charger and connect the desktop charger to the AC outlet. *NOTE: International adapters are available through Designs for Vision; refer to the list on page 37.*

The power button light will start pulsing to indicate the unit is in “Smart Charge” mode.

The status indicator (Fig. 2) will display the current state of charge. The LED will change colors as the battery charges; going from **RED** to **ORANGE** to **GREEN**. When the power button light remains steady, the unit is fully charged.



FIG. 2

You can now disconnect the cord from the power pack to run on battery. The belt clip on the rear of the holster will allow you to carry it around with you.

HOLSTER OPERATION

In addition to the holsters, Ratcheting Belt Clips have been included to allow for a full 360° rotation of the unit, even while it is attached to you. To place the belt clip on to the holster, simply slide it up over the raised circular ratchet disk until an audible 'click' is heard (*Fig. 3*). The clip on the back of the leather case is designed to clip onto a belt.

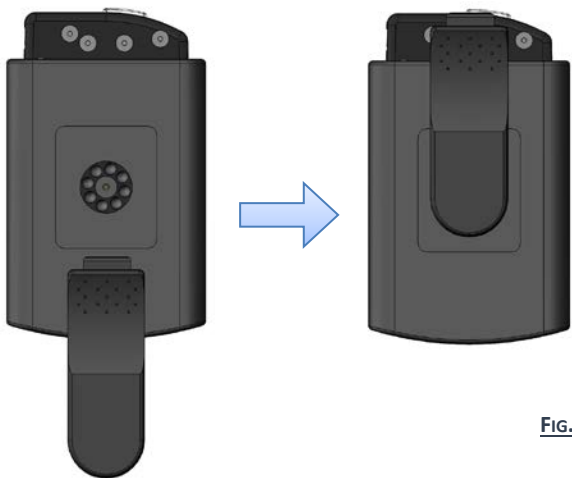
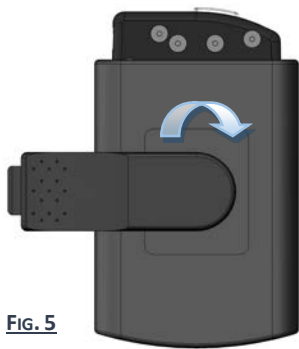
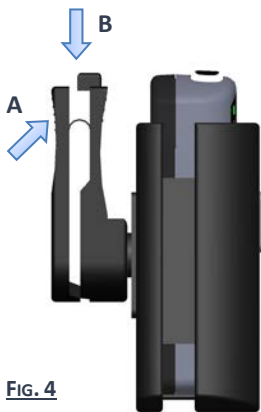


FIG. 3

Squeeze the clip together to open. Arrow A (Fig. 4) shows where to press. The power pack can rotate to your desired position.

Each increment is followed by an audible click. To remove the power pack from the clip, depress the button on the top of the belt clip while pulling up on the power pack, which is shown by arrow B (Fig. 4).



NOTE: Make sure power pack is properly seated before commencing use.

USING THE POWER LINK FEATURE

In the event that you require additional run-time, we have supplied a Power Link Cable which will allow you effectively double the number of hours your headlight will last. Turn both power packs on and simply connect two power pack units together, as shown (*Fig. 6*), and plug your headlight







FIG. 6

into either one. Intensity can be controlled by the power pack that your headlight is plugged into.

UNDERSTANDING THE STATUS INDICATOR

The LED DayLite® HDi™ incorporates an advanced status monitoring system. The following table describes what each indication signifies:

	<p>SOLID GREEN: FULLY CHARGED BATTERY</p>
	<p>SOLID/PULSING RED: LOW BATTERY</p>
	<p>FAST BLINK RED: GENERAL ERROR. PLEASE CONTACT DESIGNS FOR VISION, INC. FOR FURTHER ASSISTANCE</p>
	<p>SLOW BLINK RED: BATTERY SPENT. PLEASE CONTACT DESIGNS FOR VISION, INC. FOR FURTHER ASSISTANCE</p>

NOTE: A spent battery should not be used. Contact Designs for Vision Inc. for ordering a replacement.

The LED DayLite® HDi™ also incorporates a Low Battery Warning system. With approximately ten (10) minutes of battery power remaining, the headlight will flash three times. At five (5) minutes remaining, the headlight will flash

another three times. At 30 (thirty) seconds remaining, the headlight will flash continually until the battery is completely depleted.

REPLACING THE BATTERY

At the end of its useful life, the battery will need to be discarded and replaced with a new one. To accomplish this,



FIG. 7

you will need the hex driver supplied with the unit. Loosen the screw at the bottom of the

power pack until it is removed from the battery door. Slide

NOTE: If the battery is installed improperly, the unit will not function

the door down and out to expose the battery (Fig. 7).

Unplug the black connector on the battery on the inside of the unit.

Note: Replace with Designs for Vision,

Inc. battery only. Using unapproved batteries may not work

and will void the warranty. Insert the new battery being very careful to install in the proper orientation. Plug the battery into the connector then place the battery in the pack. Make sure all wires are tucked into the compartment. Replace door and tighten screw. *NOTE: You will need to fully charge the battery before the fuel gauge will read properly.*

USING THE ULTRAMINI[®]/DAYLITE[®]/HDI[™] HEADLIGHTS

Place the headlight onto the t-mount bracket for your frame. The headlight can be adjusted up and down to align with your point of view. The headlight can then be locked into that position using the provided driver (if equipped). Locate the hex in the locking shaft of the headlight (*Fig. 8*). Place the driver into this opening and turn clockwise to tighten the shaft. To unlock the position, loosen the shaft by turning counter-clockwise.

NOTE: The shaft will



FIG. 8

only turn a limited distance. Do not force in either direction.

Plug the headlight cable into the headlight (*Fig. 9*). The micro USB connector can only be plugged in one way. The indicator on the connector must be facing in the direction

FIG. 9



shown. Connect the large end of the headlight cable to the headlight port on the top of the power pack.

Clips and a cable wrap are also supplied to be used in conjunction with your frame to

direct the cable away from your face.

Press the power button on the front of your battery pack. The headlight will turn on at high intensity. The power button will illuminate and the status indicator will display the current state of charge. A second press of the power button will lower the light intensity of the headlight. A third press turns the power pack off.

USING THE TWINBEAM®/IR/HDI™

The TwinBeam®/IR/HDI™ headlights are available with either a DV headset or a CXL headset. Both designs incorporate two locking shafts on the adjustable arm (*if equipped*). This is designed to facilitate precise positioning (*Fig. 10*).

Connect the small end of the headlight cable to the back of the headlight. Connect the large end of the headlight cable to the headlight port on the top of the power pack. Clips are located on the headsets to direct the cable away from your face.



FIG. 10

Press the power button on the front of your battery pack. The headlight will turn on at high intensity. The power button will illuminate and the status indicator will display the current state of charge. A second press of the power

button will lower the light intensity of the headlight. A third press turns the power pack off.

The TwinBeam® IR HDi™ incorporates a motion sensor to allow for activation/deactivation of the headlight using only simple hand gestures. Located on the top of the headlight is



MOTION SENSOR

FIG. 11

the built-in motion sensor (Fig. 11). Once power is applied from the power pack, move your hand over the sensor about four

to six inches above. Wave your hand once to shut the light off, a second time to turn the light back on.

NOTE: The sensor does not turn off the power pack. In order to shut down power to the headlight, you need to press the button on the power pack.

USING THE NANO CAM HD/HDi™

NOTE: Before proceeding, plug the USB flash drive that came with your NanoCam HD/HDi™ into an available PC and run the setup file. Prior to your first use, you will need to perform the following steps to properly align and setup the camera, light (if equipped) and micro-video lens system of your NanoCam HD/HDi™:

1. MOUNTING NANO CAM HDi™ AND INSERTING CABLES
2. ALIGNING NANO CAM HDi™ WITH YOUR FIELD OF VIEW
3. FOCUSING YOUR NANO CAM HDi™
4. ALIGNING THE HEADLIGHT WITH YOUR NANO CAM HDi™

1. MOUNTING NANO CAM HDi™ AND INSERTING CABLES

Mount the NanoCam HDi™ to your frames or headset using the supplied T-Mount. Attach the HDi™ Headlight (*Fig. 12*) to the camera as shown. Plug the small connector of the headlight cable into the top of the headlight. Plug the large connector of the cable into the headlight connector on the power pack.

Double click on the camera software icon and wait for the program to start. You can now plug the USB connector from the camera into an available USB port on your PC. Once the camera connects, you should see live video on your monitor.



2. ALIGNING NANOCAM HDI™ WITH YOUR FIELD OF VIEW

While wearing the camera on your frame, look through your surgical telescopes (loupes) at the provided focusing card. *NOTE: It is helpful to have the card placed on a flat surface with the video monitor directly in front of you.* The card should be placed in the center of your field of view.

Grasp the camera and move either up or down until the video image on your monitor is centered with your vision through your surgical telescopes (loupes).

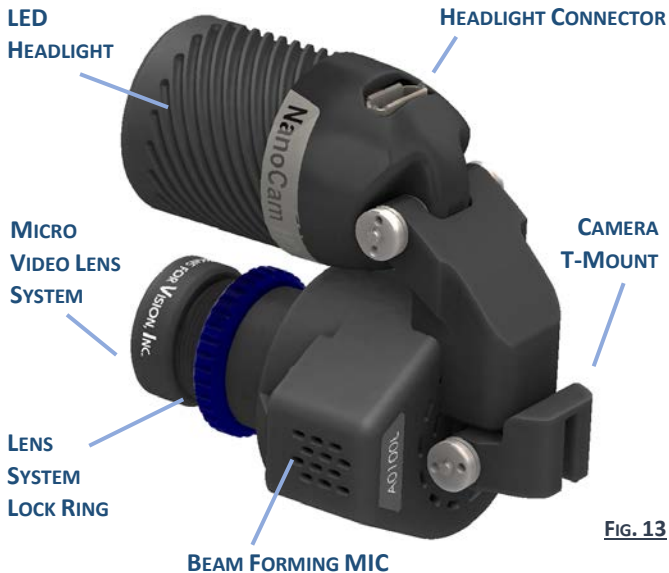


FIG. 13

NOTE: Make sure to keep your head still when shifting your view from the surgical telescopes (loupes) to the video monitor. Carefully remove your frame making sure to not shift the camera. Get the hex screwdriver included with your NanoCam HDi™. Place the driver into the opening for the locking shaft and turn clockwise to tighten. This will lock the

camera with your telescopes. Place the camera back on your face. *NOTE: Gently Pull up and down on your camera to confirm that it is locked in place.*

3. FOCUSING YOUR NANO CAM HDI™

Next, you will need to focus the micro-video lens system. Your NanoCam HDI™ comes with three magnifications of micro-video lens systems; 2.5x, 3.5x, and WA. For your convenience, the NanoCam HDI™ comes with the 2.5x lens system pre-installed. If you wish to change the magnification, carefully unscrew the micro-video lens system and replace it with one of the other magnification lens systems (*Fig. 14*).

NOTE: Be careful not to allow any dust or contaminants to enter the open camera body.

NOTE: Make sure to re-install the lens system lock ring when changing the lens system.

Rotate the micro-video lens system until the video image on your monitor is in focus. *NOTE: Rotating the micro-video lens*

FIG. 14



system clockwise decreases the focal length of the camera. Rotating the micro-video lens system counter-clockwise increases the focal length of the camera.

While holding the micro-video lens system with one hand, use your other hand to turn the lens system lock ring counter-clockwise until it locks the micro-video lens system into place. The micro-video lens systems have been optically matched with your surgical telescopes (loupes). When

properly focused, the camera will have the same magnification and depth of field as what you see through your surgical telescopes (loupes).

4. ALIGNING THE HEADLIGHT WITH YOUR NANOCAM HDi™

The final adjustment is the headlight. Get the hex screwdriver included with your NanoCam HDi™. Gently pull up and down on the headlight to place the spot of light in the center of what you see through your surgical telescopes (loupes). Shift your view from the surgical telescopes to the video monitor to confirm that the light properly fills the video image. Carefully remove your frame making sure to not shift the headlight. Place the driver into the opening for the locking shaft of the headlight and turn clockwise to tighten. This will lock the headlight with your camera.

Your NanoCam HDi™ should now be fully aligned and focused to your frame mounted telescopes. The image on your video monitor should look like the next picture (*Fig. 15*). The settings will stay locked in place for future uses.

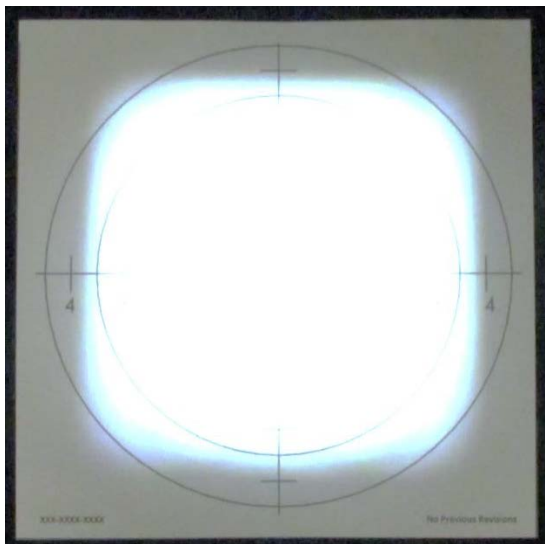
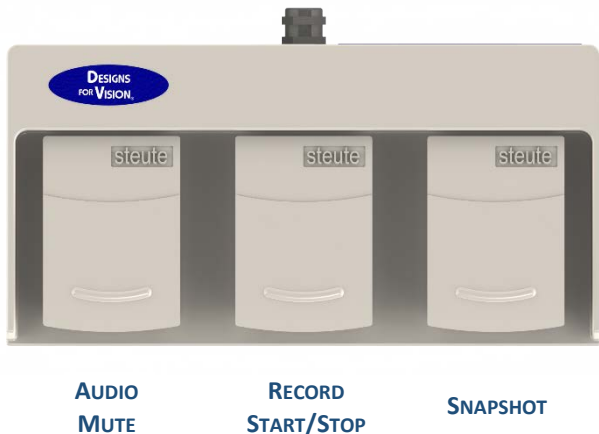


FIG. 15

FOOT PEDAL OPERATION

Your NanoCam HDi™ is available with a shielded USB foot pedal to allow for hands free operation. Once connected to a PC with the Designs for Vision, Inc.® software already installed, the foot pedal will help to control the camera functions.

FIG. 16



NOTE: For foot pedal to function, NanoCam HDi™ software has to be the active screen on your PC.

The default settings for the foot pedal are Record Start/Stop, Audio Mute and Snapshot (Fig. 16). When you press Audio Mute, you will hear an audible alert. Your camera will continue to record the video, but it will not record any audio until you deactivate it by pressing Audio Mute again.

When you press Record Start/Stop, you will also hear an audible alert. Video will be recording at full resolution and frame rate. Pressing Record Start/Stop again will stop the recording. When you press the Snapshot button, you will hear an audible sound. This indicates that a photo/bookmark has been made.









INSPECTION AND PREVENTATIVE MAINTENANCE






- Clean lenses with a standard glass cleaner and a soft, lint-free cloth, making sure not to scratch the surface.
- Not intended to be sterilized. It is recommended for disinfection that all the exposed plastic sections of the headlight, power pack and accessories be wiped with Lysol IC surface disinfectant/cleaner or an equivalent plastic-safe cleaner. *Note: Do not use alcohol, phenol, ammonia, or iodine complex solutions*
- Wipe the sections rather than spraying onto plastic parts. *Note: Do not let liquids enter openings or ports.*

Do not immerse parts in solutions. Using solutions other than recommended may void warranty. Allowing liquids to enter openings or ports may void warranty.

- Wipe cables with plastic-safe cleaners, if necessary. Do not allow cleaners to get onto the cable connectors as it may cause the electrical terminals to corrode
- Internal batteries must be replaced every 24 months to ensure proper operation
- For the LED DayLite® TwinBeam IR HDi™, be sure to wipe the sensor on the top of the unit before each use
- Always examine all components for damage before each use. Examine all cables for broken or frayed wires before each use
- It is recommended to keep the NanoCam HDi™ and TwinBeam® headlights in the supplied carrying cases to provide proper protection

DESCRIPTION OF VARIOUS SYMBOLS

	<i>ATTENTION / CAUTION</i>
	<i>CAUTION: HOT SURFACE</i>
	<i>INDICATES CONFORMITY WITH MDD 93/42/EEC ANNEX VII</i>
	<i>INDICATES WHERE THE UNIT CAN BE TURNED ON AND OFF</i>
	<i>INDICATES BATTERY STATE OF CHARGE</i>
	<i>INDICATES WHERE THE UNIT CAN BE CHARGED</i>
	<i>READ ACCOMPANYING DOCUMENTS</i>
	<i>WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) DIRECTIVE SYMBOL</i>

	<i>ELECTRICAL SHOCK HAZARD</i>
	<i>EQUIPMENT CLASS</i>
	<i>TEMPERATURE LIMITS</i>
	<i>HUMIDITY LIMITS</i>
	<i>ATMOSPHERIC PRESSURE LIMITS</i>

REPLACEMENT PARTS

DESCRIPTION	PART NUMBER
UltraMini™	4902-0000-0002
UltraMini™ HDi™	4902-3000-0001
USB DayLite®	4702-0019-0002
DayLite® HDi™	4702-3000-0001
USB TwinBeam® (w/DV Headset)	4709-3000-0000
USB TwinBeam® (w/ CXL Headset)	4709-3005-0000
TwinBeam® HDi™	4709-3000-0001
TwinBeam® IR HDi™	4719-3000-0001

DV Headset w/ T-mount	4709-3000-0005
CXL Headset w/ T-mount	4709-3005-0005
NanoCam HD™	4003-0000-0003
NanoCam HDi™	4003-3000-0001
Battery	4912-0000-1018
Li-Ion Battery Charger	4912-0000-2019
United States Plug & Cord Set	4706-0000-0038
European Plug & Cord Set	4706-0000-0030
Australian Plug & Cord Set	4706-0000-0032
South African/Indian Plug & Cord Set	4706-0000-0033
English Fused Plug & Cord Set	4706-0000-0034
Japanese Plug & Cord Set	4706-0000-0037
Headlight Cable	4911-0001-0022
Power Link Cable	4912-0000-0019

ELECTROMAGNETIC INFORMATION

This equipment is designed to comply with IEC 60601-1-2. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment ON and OFF. Try to correct the interference using one or more of the following:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Consult Designs for Vision, Inc. for help

Table 201 – Guidance and Manufacturer’s Declaration – Emissions
All Equipment and Systems

Guidance and Manufacturer’s Declaration – Emissions

The LED DayLite[®] HDi[™] is intended for use in the electromagnetic environment specified below. The customer or user of the LED DayLite HDi[™] should insure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF Emissions CISPR 11	Group 1, Class A	The LED DayLite [®] HDi [™] 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.
Harmonics IEC 61000-3-2	Class A	The LED DayLite [®] HDi [™] is suitable for use in all establishments (not including domestic) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

**Table 202 – Guidance and Manufacturer’s Declaration – Immunity
All Equipment and Systems**

Guidance and Manufacturer’s Declaration – Immunity			
The LED DayLite® HDi™ is intended for use in the electromagnetic environment specified below. The customer or user of the LED DayLite® HDi™ should ensure that it is used in such an environment.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±15kV Air	Floor should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV 100kHz Repetition frequency	±2kV 100kHz Repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV Line-to-line ±0.5kV, ±1kV, ±2kV Line-to-ground	±1kV Line-to-line ±2kV Line-to- ground With client modifications	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage Dips/Dropout</p> <p>IEC 61000-4-11</p>	<p>0% U_T: for 0.5 Cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°</p> <p>0% U_T: for 1 Cycle and</p> <p>70% U_T: for 25/30 Cycles</p> <p>Single Phase: at 0°</p>	<p>0% U_T: for 0.5 Cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°</p> <p>0% U_T: for 1 Cycle and</p> <p>70% U_T: for 25/30 Cycles</p> <p>Single Phase: at 0°</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p> <p>If the user of the LED DayLite® HDi™ requires continued operation during power mains interruptions, it is recommended that the LED DayLite® HDi™ be powered from an uninterruptible power supply or battery.</p>
<p>Power Frequency</p> <p>50Hz or 60 Hz</p> <p>Magnetic Field</p> <p>IEC 61000-4-8</p>	<p>30 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</p>

**Table 204 – Guidance and Manufacturer’s Declaration – Emissions
Equipment and Systems that are NOT Life-Supporting**

Guidance and Manufacturer’s Declaration – Emissions

The LED DayLite® HDi™ is intended for use in the electromagnetic environment specified below. The customer or user of the LED DayLite® HDi™ should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted Disturbances induced by RF Fields</p> <p>IEC 61000-4-6</p>	<p>3 V</p> <p>0.15 MHz-80 MHz</p> <p>6 V in ISM bands between 0.15MHz and 80MHz</p> <p>80% AM at 1 kHz</p>	<p>3 V</p> <p>0.15 MHz to 80 MHz</p> <p>6 V in ISM bands between 0.15MHz and 80MHz</p> <p>80% AM at 1 kHz</p>	<p>Interference may occur in the vicinity of equipment containing a transmitter.</p>
<p>Radiated RF EM Fields</p> <p>IEC 61000-4-3</p>	<p>3 V/m</p> <p>80MHz-2.7GHz</p> <p>80AM at 1KHz</p>	<p>3 V/m</p> <p>80MHz-2.7GHz</p> <p>80AM at 1KHz</p>	

Table 206 – Recommended Separation Distances between portable and mobile RF Communications equipment and the LED DayLite® HDi™ Equipment and Systems that are NOT Life-Supporting

Recommended Separations Distances for the LED DayLite® HDi™

The LED DayLite® HDi™ is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the LED DayLite® HDi™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the LED DayLite® HDi™ as recommended below, according to the maximum output power of the communications equipment.

Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Max Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse Modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation ^{b)} 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800-900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation ^{b)} 18 Hz	2	0,3	28
870						
930						

1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation b) 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation b) 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation b) 217 Hz	2	0,3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the LED DayLite® HDi™ may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARNING: 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.

WARNING: 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.

WARNING: 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 LED DayLite® HDi™, including cables specified by Designs for Vision, Inc. Otherwise, degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE: The LED DayLite® HDi™ may be adversely affected by EM DISTURBANCES possibly resulting in a loss of light output.

NOTE: The LED DayLite® HDi™ is intended to be used during HF SURGERY. Keep headlight cable securely attached to the body using supplied clips. Headlight cable should not come in contact with HF EQUIPMENT/CABLES. If interference occurs, increase separation distance between the LED DayLite® HDi™ and the HF EQUIPMENT.

WARRANTY

The UltraMini[®], UltraMini[®] HDi[™], USB DayLite[®], DayLite[®] HDi[™], TwinBeam[®], TwinBeam[®] HDi[™] and TwinBeam[®] IR HDi[™] headlights are warranted against imperfections and defects in materials and workmanship for four years. The NanoCam HD[™] and NanoCam HDi[™] is warranted against imperfections and defects in materials and workmanship for three years. The power pack is warranted for two years. The internal batteries, charger, and cables are warranted for one year. The power pack electronics are warranted for two years.



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