

# V1 Product Manual

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## **Description of V1**

The V1 is a compact headlight that provides focused lighting directed at a point of interest and/or area of operation. The device consists of the V1 headlight, V1 cable, and approved power banks. The device includes voice control firmware which allows the brightness to be adjusted incrementally using voice commands “brighter” and “dimmer”. Heads-up detection decreases the brightness to its lowest setting when the light is raised above a pre-specified angle. Adaptive brightness can be enabled which allows the V1 to automatically adjust light output based on ambient lighting. These settings can be enabled/disabled with the associated mobile application.

## **Specifications**

- Weight: 15g
- Device dimensions: 25.5mm x 25.5mm x 45mm
- Maximum illuminance: 200,000 lux @13” working distance
- Minimum illuminance: 10,000 lux @13” working distance
- Light source: Light Emitting Diode
- Light color: 5700K
- Battery life: 6 hrs nominal
- Battery charge time: 60 minutes

## **Intended Use**

The V1 LED lamp is indicated for use in medical, dental, and veterinary procedures where focused illumination is required. It is intended to provide lighting directed at the point of interest and/or area of operation. The V1 headlight is intended only to be used by professionals trained to perform the medical procedure being conducted.

## **Contraindications**

None

## **Warnings and Precautions**

### **Warnings**

- Operator must consider usage circumstances, condition, variables, and unique surface/patient sensitivities, including but not limited to chemical, genetic, pharmacological, photosensitivity, thermal sensitivity, and preexisting conditions, which may make even typical safe working distances unsuitable and potentially unsafe.
- Always dispose of power banks according to local, state, and federal laws and regulations. Improper disposal can lead to environmental harm.
- Only use approved accessories. Use of accessories other than those specified or provided by Voxel Surgical could result in improper operation.

- Do not force any screws or adjustable components on the device. This can lead to damage to the device or components and improper securement of the device.
- During normal use the headlight, power bank, and charger may be warm to the touch but should not be uncomfortable. If the unit becomes uncomfortably warm, immediately stop using the device and report the issue to Voxel customer service.

#### Precautions

- Handle device and accessories with care. Do not drop device, accessories, or packaging as it may damage or break the device.
- Store case in a secure, clean, and dry location. Failure to do so may result in damage or malfunction of the device.
- Always examine device and components for damage and to ensure the proper function prior to use.
- Do not use damaged accessories and contact Voxel Surgical for replacements if components are damaged or not functional.
- Do not sterilize device or components.
- Do not use this equipment adjacent to or stacked with other equipment. If this use is necessary, confirm proper operation of both this device and nearby equipment prior to use.
- Power down device after end of each use by removing cable from power bank.
- Disinfect all exposed surfaces of the headlight, cables, power bank, and accessories with only Lysol IC surface disinfectant/cleaner.
- Do not use alcohol, phenol, ammonia, or iodine complex solutions to disinfect device and/or components.
- Do not allow liquids to enter into openings or ports.
- Do not immerse parts in solutions.
- Ensure headlight is accurately adjusted to the correct field of view prior to clinical use. This can be achieved by manually moving the headlight laterally and using the hex driver to adjust the angle adjustment screw.
- The Voxel V1 may be adversely affected by electromagnetic disturbances.

#### **FCC Compliance Statement**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**CAUTION:** The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

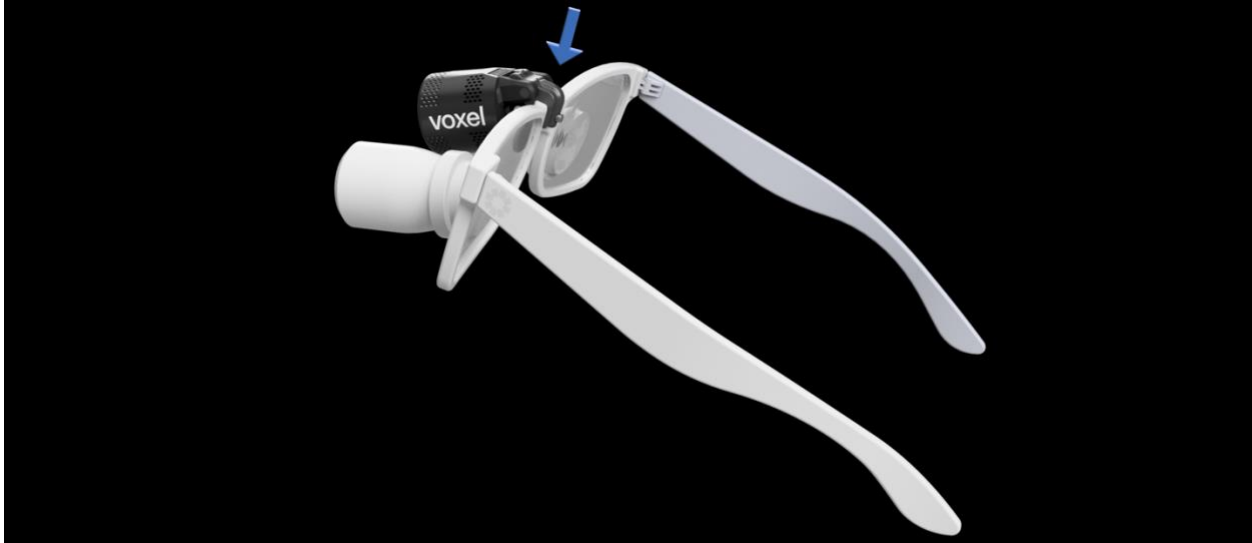
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

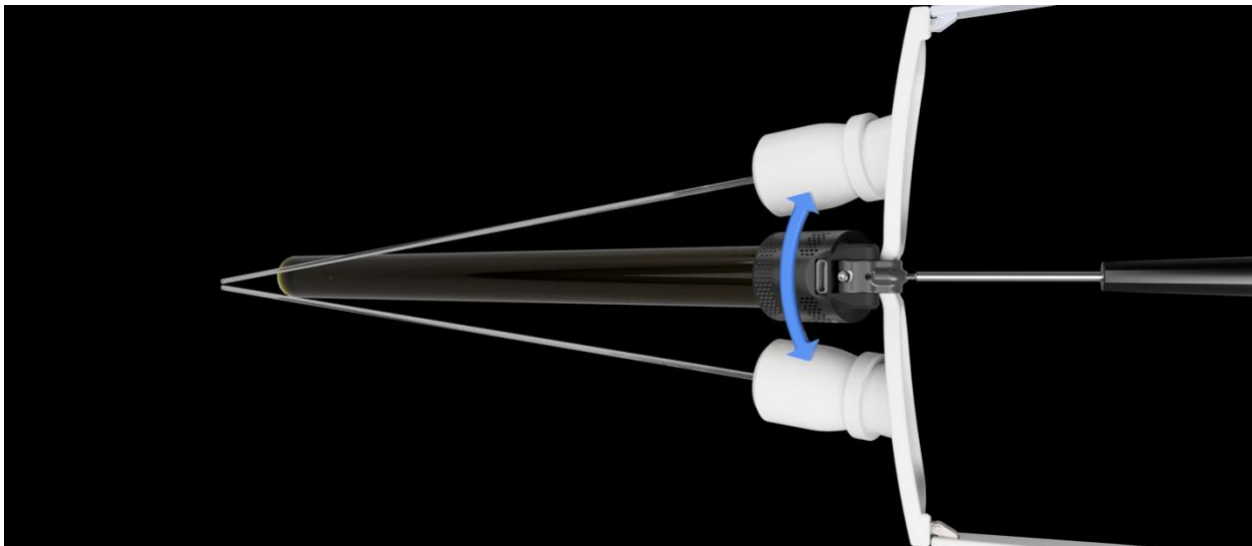
### **Instructions for Use/Directions for use**

#### **Unpacking + Setup**

- Remove case from box and properly dispose of any packaging material.
- Carefully remove the headlight, power cable, charging cable, power banks, and transformer from the case.
- Loosen set screw on the top of the headlight with associated hex driver.
- Place light onto bridge of glasses/loupes.
  - Note: Voxel V1 is only compatible with Design for Visions and Orascoptic loupes.



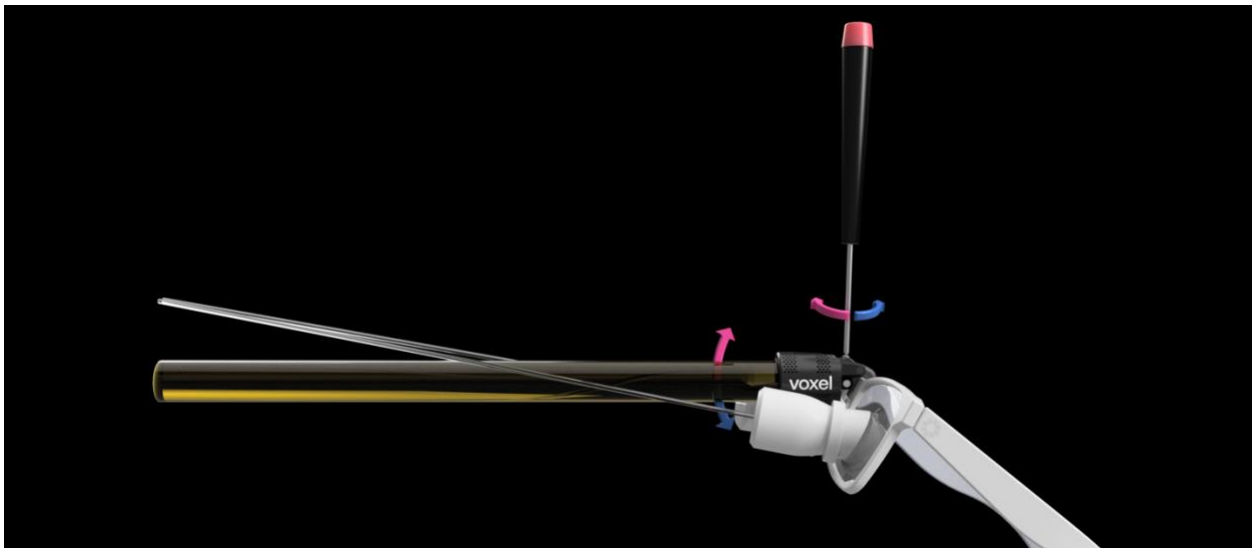
- Perform lateral angle adjustments to align field of view with focus of light.



- Tighten set screw until headlight is securely attached, but do not force the screw in either direction.



- Perform superior and inferior angle adjustments using the angle adjustment screw to align field of view with focus of light. Do not force screw in either direction.



- Plug Voxel approved 90-degree USB-C cable into USB-C port on top of headlight.
- Attach associated eyewear retainers to glasses/loupes.
- Route cable along temporal arm band of glasses/loupes.
- Secure cable on glasses using included rubber band.
- Secure cable at back of head using loom on the eyewear retainers.
- Place power bank in provided clip and secure on waist.
- Plug USB-C cable into USB-C port on power bank.
- Device is ready for use.

## Mobile Application Setup + Use

- Download Voxel App from either App Store or Google Play.
- Open app.
- Follow instructions on screen to pair headlight to mobile application.
- Turn on desired settings (voice control, head-position control, adaptive-brightness).
- Use slider to control brightness as desired.

## Device Control During Use

- Voice Control
  - Voice control option can be enabled or disabled using the associated mobile application.
  - If enabled, use phrases “brighter” or ”dimmer” to increase or decrease the brightness respectively. When the headlight reaches maximum or minimum brightness, it will flash once to signal it has reached the limit.
- Heads-up detection
  - Heads-up detection can be enabled or disabled using the associated mobile application.
  - If enabled, when the headlight is raised above the prespecified angle in the application the light will decrease to minimum brightness.
  - When the headlight is lowered below the same angle it will increase to the previous brightness level.
  - If voice commands are enabled, invoking the “brighter” command after the light has dimmed upon reaching a prescribed head position will return the light to the original brightness for the duration that the user’s head remains within the same quadrant of head position control.

## Battery changeouts and charging

- Remove power bank from pocket or waist clip.
- Remove cable from power bank.
- Place discharged power bank on charger with associated cable and wall transformer.
  - a. Note: only use Voxel Surgical approved cable and wall transformer
- Retrieve replacement power bank.
- Connect cable to replacement power bank.
- Place power bank in pocket or on waist clip.

## Routine Shutdown and Storage

- Remove glasses from head.
- Remove cable from power bank, light will power off automatically.

- Disinfect all exposed surfaces of the headlight, cables, power bank, and accessories with Lysol IC surface disinfectant/cleaner.
- Do not use alcohol, phenol, ammonia, or iodine complex solutions.
- Do not allow liquids to enter into openings or ports.
- Do not immerse parts in solutions.
- Remove cable from power bank.
- Retrieve case and place power bank into its designated slot.
- Place glasses and headlight in large open cavity.
- Loop cable and place on top of glasses.
- Close zipper on case and store in a secure, clean, and dry location until next use.

#### Removing headlight from glasses

- Remove cable from headlight.
- Use hex driver to turn set screw counterclockwise to loosen the frame clamp.
- Remove headlight from bridge of glasses.
- Remove cable from loom on eyewear retainers.
- Remove rubber band retainer from arm of glasses.
- Unplug cable from power bank.
- Coil cable and place cable, headlight, power bank and accessories in case.

#### Disposal

- Dispose of device, V1 power bank, and accessories according to hospital procedures and applicable local, state, and federal laws and regulations

#### **Maintenance**

The V1 does not require any ongoing maintenance. However, inspect the device and all accessories for damage and/or wear prior to each use. Ensure device is fully functional before each use. Do not use if inspection reveals any damaged or broken components or accessories. Keep the V1 in the provided storage case after use, in a safe and secure location for proper protection.

#### **Warranty**

The V1 headlight is warranted against imperfections and defects in materials and workmanship for 10,000 usage hours. The power bank, charger, and cables are warranted for two years. Any damage caused by improper maintenance or usage as described in the manual may not be covered by the warranty.