Product Overview and Description

The King Vision® Video Laryngoscope is a portable, battery operated, rigid, digital video laryngoscope system that incorporates an integrated reusable display and choice of disposable blades designed to visualize the airway while aiding in the placement of airway devices.

Product Components

This King Vision Video Laryngoscope consists of two primary components:

1. A durable, integrated reusable display (Fig. 1, #1).
2. A choice of disposable blades: with or without a channel for tracheal tube guidance (Fig. 1, #2 and #3).

An optional video-out cable for connection to an external monitor is also available.

None of the product components are made with natural rubber latex.

Note: all components are supplied clean, non-sterile, ready to use.

Reusable Display (Fig. 1, #1)

The reusable component of the King Vision Video Laryngoscope is a durable, high quality, portable, battery operated display with an OLED (Organic LED) screen. It incorporates digital technology to receive images from the distal tip of the disposable blade and displays the image on the integrated full color, anti-glare screen. The reusable display has an on/off switch (Fig. 1, #4), a battery indicator light (Fig. 1, #5) and a video-out port (Fig. 1, #6). It automatically corrects for white balance and incorporates an advanced power.
management system. Power is provided by three AAA batteries housed in the battery compartment (Fig. 1, #7)

**Single Use Blades (Fig. 1, #2 and 3)**

The disposable component of the King Vision Video Laryngoscope consists of a choice of disposable blade versions:

<table>
<thead>
<tr>
<th>The King Vision Channeled Blade (Fig. 1, #2)</th>
<th>The King Vision Standard Blade (Fig. 1, #3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “Channeled” Blade incorporates a guiding channel to facilitate delivery of an endotracheal tube (ETT) to vocal cords. Channeled Blades accommodate a specific range of ETT sizes. No stylet is needed.</td>
<td>The “Standard” Blade contains no guiding channel. As such, these blades will likely require the use of a stylet to assist in delivering the ETT to the vocal cords.</td>
</tr>
</tbody>
</table>

Both blade versions connect to the reusable display, completing the King Vision Video Laryngoscope system and transmit the image to the display when turned on. These blades include an LED light source (Fig. 1, #8) and CMOS camera (Fig. 1, #9) housed in the distal tip. An anti-fog coating is provided at the distal tip to prevent condensation from obscuring the image.

Sizing is intended to be consistent with standard rigid laryngoscopes. Accordingly, size 3 blades (both channeled and standard) should be appropriate for the average adult patient.

**Indications For Use:**

The King Vision Video Laryngoscope is a rigid laryngoscope used to examine and visualize a patient’s upper airway and aid in the placement of a tracheal tube.

![WARNINGS AND PRECAUTIONS](image)

The King Vision Video Laryngoscope should only be used by individuals who have been trained and authorized to provide patient care with this device (intubation).

**Warning:** Do not store batteries in the King Vision Display for long periods of time as they may leak and cause damage to the Display.

The King Vision Display may experience a small amount of current leakage if stored with batteries, even when the Display is turned off, as such, it is recommended that the user replace the batteries in the unit as directed by the battery indicator light or on a quarterly basis if not used regularly.

**Warning:** No modification of this equipment is allowed.

**Warning:** The King Vision blade contains a light source that could cause the blade surface temperature to exceed 41°C when used near the upper limit of the operating temperature range specified for this product (e.g., during one test, 42.1 °C was measured on the blade surface in an operating temperature of 40 °C). Patient tissue damage can occur from direct contact with surfaces exceeding a temperature of 41°C for a prolonged period of time. As such, patient contact time should be minimized when used near the upper limit of the operating temperature range.
CAUTIONS:

The King Vision Display is designed to be used ONLY in conjunction with King Vision Blades.

Direct visualization of the vocal cords (direct line of sight) from outside the mouth should not be expected with the King Vision Video Laryngoscope.

Do not submerge the King Vision Display in any liquid as this can damage the display. Failure to follow the cleaning and preparation for use instructions may compromise the performance of the system and may void the warranty.

Do not put pressure on the teeth with the King Vision Video Laryngoscope.

Do not use excessive force to insert the King Vision Blade into the mouth.

Reported complications of endotracheal intubation using video laryngoscopy include: mucosal injuries, perforations, tears, edema, sore throat, TMJ injuries, and nerve injury.

Always confirm placement of the endotracheal tube using accepted methods.

Not suitable for use in the presence of flammable anesthetics.

Before use, the outer surface of each blade should be checked for unintended sharp edges, protrusions, visible cracks, or rough surfaces which may cause harm; if present use a different blade.

If an unpackaged blade is dropped prior to use, discard and replace with a new clean blade.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

Acquiring an Image

Important: The King Vision Display must be “off” before attaching a Blade; otherwise the video image will become distorted. If this happens, simply turn the Display OFF then back ON. If, after the pre-use check with the blade attached, the video screen on the Display does not show moving images, follow these steps:

1) Check to make sure the Display and Blade are properly attached to each other by separating them and then reattach.
2) Cycle the power OFF, then back ON.
3) Replace the Blade.
4) Replace the Display.
   Note: If the King Vision Video Laryngoscope is in the patient’s mouth when this occurs, remove it before troubleshooting the loss of image.

General Recommendations

New and first-time users should practice using the King Vision Video Laryngoscope in a mannequin before clinical use of the product.

Prior to use for a difficult airway, users of the King Vision Video Laryngoscope will benefit from use on patients with normal anatomy.
The King Vision Display should be inspected prior to each use by the user. If visible signs of damage or problems with the Display are found, replace with a new unit.

Battery Installation / Replacement

Three (3) Disposable Size AAA Alkaline Batteries are Recommended

- Open the battery compartment on the reusable King Vision Display (Fig. 1, #7), found on the handle area that inserts into the Blades. Slide the cover in the direction of the arrow.
- Dispose of used batteries in accordance with local environmental policies. Do not mix new and used batteries together in the Display.
- Install / replace the 3 AAA batteries on top of the pull ribbon following the guide inside the battery well or on inside battery cover of the Display.
- Replace the battery cover by sliding it up towards the video screen; it should click/snap securely into place.

Pre-use Battery Check

- Press the POWER button Ø (Fig. 1, #4) on the back of the King Vision Display.
- The Display should turn ON immediately. Note: No image will be displayed on the screen without an attached Blade.
  - The GREEN LED battery indicator light (Fig. 1, #5) indicates the Display is ready for use.
- Important: If the LED battery indicator light is FLASHING RED, the batteries must be replaced as soon as possible as a limited amount of battery life remains.
- The Display can be turned “OFF” manually by pressing and holding the POWER button. If a King Vision Blade is not attached to the Display, it will automatically turn off in approximately 20 seconds.

Step by Step Instructions

Important: The King Vision Display must be “OFF” before attaching a Blade; otherwise, the video image will become distorted. If this happens, simply turn the Display “OFF” then back “ON”.

STEP 1 – Preparing the King Vision Video Laryngoscope (the Display and Blade combination) for use

- Choose the style of Blade (Standard or Channeled) to be used.
- Install the Display into the Blade (only goes together one way). Listen for a “click” to signify that the Display is fully engaged with the Blade. Note that the front and back of the parts are color-coded to facilitate proper orientation.
### Using The King Vision Channeled Blade

<table>
<thead>
<tr>
<th>The size #3 Channeled blade is designed to be used with standard ETT sizes 6.0 to 8.0. No stylet is needed.</th>
</tr>
</thead>
</table>

Lubricate the ETT, the guiding channel of the Channeled Blade and the distal tip of the Blade using a water soluble lubricant. Take care to avoid covering the imaging element of the blade with lubricant.

The ETT may be preloaded into the guiding channel with its distal tip aligned with the end of the channel. Note that the ETT tip should not be evident on the screen when loaded properly. Alternatively, the ETT can be inserted into the channel after the blade has been inserted into the mouth and the vocal cords have been visualized.

### Using The King Vision Standard Blade

<table>
<thead>
<tr>
<th>The size #3 Standard blade is used when integral guidance of the ETT is not indicated. In this case, a stylet will likely be necessary.</th>
</tr>
</thead>
</table>

Lubricate the distal tip of the Standard Blade using a water soluble lubricant. Take care to avoid covering the imaging element of the blade with lubricant.

The ETT and stylet should be lubricated and the stylet pre-loaded into the ETT in the same manner as with other intubations where a stylet is used.

User tip: Shaping the ETT with a pre-loaded stylet to match the blade curvature may be helpful.

### Step 2 – Powering On

- Press the POWER button (Fig. 1, #4) on the back of the King Vision Display.
- The King Vision Display should turn “ON” immediately AND Display shows a moving image.
- Confirm the imaging of the King Vision is working properly. If not, stop and refer to the “Acquiring an Image” section.

**IMPORTANT:** If the LED Battery indicator light (Fig. 1, #5) in the upper left hand corner of the King Vision Display is FLASHING RED, the battery life remaining is limited and the batteries should be replaced as soon as possible.

### Step 3 – Insertion of King Vision Blade into the Mouth

- Open the patient’s mouth using standard technique.
- In the presence of excessive secretions/blood, suction the patient’s airway prior to introducing the Blade into the mouth.
- Insert the Blade into the mouth following the midline. Take care to avoid pushing the tongue towards the larynx.
- As the Blade is advanced into the oropharynx, use an anterior approach toward the base of the tongue. Watch for the epiglottis and direct the Blade tip towards the vallecula to facilitate visualization of the glottis on the Display’s video screen. The King Vision Blade tip can be placed in the vallecula like a Macintosh blade or can be used to lift the epiglottis like a Miller blade. For best results, center the vocal cords in the middle of the Display’s video screen.
- If the lens becomes obstructed (e.g., blood/secretions), remove the Blade from the patient’s mouth and clear the lens.
- Avoid putting pressure on the teeth with the King Vision Video Laryngoscope.
STEP 4 – ETT Insertion

<table>
<thead>
<tr>
<th>Advance the ETT (Channeled Blade)</th>
<th>Insert the ETT/Stylet (Standard Blade)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After you can see the vocal cords in the center of the King Vision Display, advance the ETT slowly and watch for the cuff to pass through the vocal cords. Note that minor manipulation of the blade may be needed to align the ETT tip with the vocal cords.</td>
<td>After you can see the vocal cords on the King Vision Display, insert the ETT with pre-loaded stylet into the mouth using a lateral approach. Once the ETT tip has reached the posterior pharynx, manipulate the ETT to direct its tip toward the vocal cords. Advance ETT tip just through the cords then retract the stylet prior to advancing the ETT into position in the trachea with the cuff below the cords. Fully remove the stylet.</td>
</tr>
</tbody>
</table>

User Tips for ETT Advancement into the Trachea

The most common issue associated with ETT placement with any video laryngoscope is that the blade tip has been advanced too far; there may be a good close-up image of the vocal cords, but the ETT cannot be advanced because the blade/camera is obstructing ETT passage. To address this:

a. Place the Blade tip in the vallecula or,
b. If too close to the vocal cords, withdraw the Blade slightly and gently lift in an anterior direction prior to attempting to advance the ETT.

Other Tips:
- If the ETT tip is deflected off to the right due to the right aryepiglottic fold or arytenoid cartilage, twist the ETT counterclockwise 90° to deflect left toward the laryngeal vestibule.
- Use Parker ETT to assist in centering the bevel to enter the laryngeal vestibule.
- With the channeled Blade, manipulate the handle to direct the ETT tip toward the laryngeal vestibule (usually toward the left), then return to midline to advance through the vocal cords.
- With the standard Blade, adjust the ETT/stylet curve to match the Blade curvature. For a more anterior larynx, a sharper bend may be appropriate.
- With the standard Blade, a retromolar approach with the ETT may facilitate intubation and may reduce the need to form the ETT/stylet with a sharper bend.

STEP 5 – Blade Removal

<table>
<thead>
<tr>
<th>Removing The King Vision Channeled Blade</th>
<th>Removing The King Vision Standard Blade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilize/hold the ETT laterally and remove the King Vision Video Laryngoscope from the mouth by rotating the handle toward the patient’s chest. As the blade exits the mouth, the ETT should easily separate from the flexible lateral opening of the channel.</td>
<td>Stabilize/hold the ETT laterally and remove the King Vision Video Laryngoscope from the mouth by rotating the handle toward the patient’s chest.</td>
</tr>
</tbody>
</table>

- Turn off Display by pressing and holding the POWER button ① (Fig. 1, #4).

Note: Always confirm placement of the endotracheal tube even after visual intubation has been performed.
STEP 6 – Separation and Disposition of the King Vision components after use:

After the procedure is complete, separate the King Vision Display from the Blade. Dispose of the Blade following local protocol and clean/disinfect the Display.

Note: Do not dispose of the King Vision Display!

CLEANING and DISINFECTING of the Reusable King Vision Display

CAUTION:
- Do not submerge the King Vision Display in any liquid as this can damage the Display.
- Do not reprocess any device suspected of being exposed to Creutzfeldt-Jakob Disease (CJD) or variants.

The King Vision Display is designed for easy cleaning and disinfection. The surfaces of the Display are specifically designed to allow proper cleaning without the need for any specialized equipment or supplies.

The King Vision Display is intended to have minimal direct patient contact during normal use.

CLEANING STEPS

If the Display is visibly soiled or contamination is suspected, follow the cleaning steps outlined below:

- To prevent liquid from entering the King Vision Display, orient the device with the video screen above the battery compartment (upright/vertical orientation).
- Prepare an enzymatic cleaning solution such as ENZOL (Cidezyme®) in accordance with the manufacturer’s instructions. Clean the entire outer surface of the Display with wipes or gauze that have been moistened (not dripping wet) with the cleaning solution. A cotton swab may be used to clean the crevices of the purple sealing gasket and the ON / OFF button. This cleaning step should last at least 2 minutes. After 2 minutes replace wipe or gauze and repeat for an additional 2 minutes or until all visible soil has been removed. Take care to avoid getting fluid inside the opening at the bottom of the battery compartment where the electrical connection is located.
  - If the video-output connection (Fig. 1, #6) was used, be sure to clean the video port cover and cable.
- Remove the battery cover (Fig. 1, #7) and clean the outer ledge on either side of the battery compartment with a cotton swab, taking care to avoid the batteries and their contacts. Clean the battery cover.
- After cleaning, remove any residue with a damp wipe or gauze.
- Use a dry wipe/gauze to remove water or allow the device to air dry.
- Replace battery cover.

DISINFECTION STEPS

To disinfect, follow the steps listed below:

Note: During the disinfection process, orient the Display with the video screen above the battery compartment (upright/vertical orientation). Do not submerge the display.

- Before removing the battery cover (Fig. 1 #7) from the display, wipe the outside of the display using a fresh Super Sani-Cloth wipe. Ensure all hard to reach areas are thoroughly wetted with the disinfectant for a minimum of 10 minutes, replacing the wipe every 2 minutes.
During the minimum 10 minute disinfection, wipe the outer surface of the display using a fresh Super Sani-Cloth wipe, paying attention to the ON / OFF button and the purple gasket.

During the minimum 10 minute disinfection, remove the battery cover and wipe the display stem and the battery cover using a Super Sani-Cloth wipe. Ensure that the outer ledges on either side of the battery compartment are thoroughly disinfected, taking care to avoid the batteries and their contacts. Concentrate on the inside rim of the battery compartment and wipe along the bottom of the purple gasket. Note: Take care to avoid getting fluid inside the opening at the bottom of the battery compartment.

Allow the display and battery cover to thoroughly air dry.

If the video-output connection (Fig. 1, #6) was used, be sure to disinfect the video port cover and cable.

- After the articles are dry, use sterile gauze moistened with sterile water to thoroughly wipe the display, the outer ledges on either side of the battery compartment, the bottom of the purple gasket and the battery cover until no evidence of disinfectant remains.
- Allow the articles to air dry completely; reinstall the battery cover to close the battery compartment.
- Store the King Vision Display in the supplied storage case or other similar clean pouch, bag or tray to protect from the environment until it is used again.

Note: The King Vision Display materials are also compatible with Cidex®, Cidex Plus® or Cidex OPA® or 70% isopropyl alcohol. When using these disinfectants, follow the disinfectant manufacturer’s instructions for proper contact conditions and time of exposure. Do not submerge. Use wipes/gauze to apply the disinfectant to the surface of the King Vision Display for the time required. Use wipes/gauze moistened with sterile water to remove residue and allow to air dry after disinfection.

Note: Use proper cleaning and disinfection technique described above. Do not Autoclave, immerse this device in any liquid or expose to ETO or any other sterilization method. These actions will damage the King Vision Display and void the warranty.

Product identification PART NUMBERS

King Vision Display and Kit part numbers:

KVIS01
1 each – King Vision Display
1 each – Protective Case for the Display
3 each – AAA Batteries

KVLKIT3
1 each – King Vision Display
1 each – Protective Case for the Display
3 each – AAA Batteries
4 each – King Vision Blades, Size 3, Adult (3 Channeled, 1 Standard)

King Vision Blade Part Numbers:

Standard Style Blade:
KVL03
10 each (1 case) – King Vision Blade, Standard, Size 3, Adult

Channeled Style Blade
KVL03C
10 each (1 case) – King Vision Blade, Channeled, Size 3, Adult; for use with ETT sizes 6.0 to 8.0 mm I.D.
Accessory for the King Vision Video Laryngoscope:

KVCABL 1 each – Video-output Cable*

* The Display video-output may be connected to UL/IEC 60601-1 certified devices with a standard analog (RCA Style) port and NTSC video signal input; no additional peripheral devices should be connected. Only the KVCABL should be used. Other cables will not function properly, may damage equipment and may void the warranty.

LIMITED WARRANTY for the King Vision Display

King Systems warrants the King Vision Display to be free of manufacturing defects for a period of one (1) year from the date of receipt. King Systems will not be responsible for repair/replacement costs beyond the warranty period.

All warranty claims require the owner to:

- Keep track of the date received. It is the date of receipt, not the date of first clinical use that begins the warranty period.
- Provide the original purchase order number or other “proof of purchase”. Call King Systems customer service at 1-800-262-8462 to receive a Return Goods Authorization (RGA) number. International customers should call customer service at 1-410-768-6464.
- Provide the above information along with the non-functional King Vision Display for any warranty claims.

With the exception of opening the battery compartment to replace batteries, there are no user serviceable parts within the Display. Opening of the Display housing will void any remaining warranty. Warranty does not cover breakage resulting from abuse or misuse.

IMPORTANT: Do not Autoclave, immerse this device in any liquid or expose to ETO or any other sterilization method. These actions will damage the King Vision Display and void the warranty.

Do not submerge the King Vision Display in any liquid as this can damage the display. Failure to follow the cleaning and preparation for use instructions may compromise the performance of the system and may void the warranty.

SPECIFICATIONS

KING VISION DISPLAY:

Display size: 2.9” X 5.8” X 1.4”
74 mm X 147 mm X 36 mm

Weight (without batteries): 95 grams

Display Screen: 2.4 inches (6.1cm) diagonal OLED color display with anti-reflective coating; 320 X 240 (QVGA) pixels per frame refreshing at 30 FPS with viewable angle up to 160°.

Internal Power Source: Use three (3) “Alkaline” AAA batteries for the best overall performance.

The King Vision Display can only be powered by AAA size batteries; an external power source is not available.
Power Management: The Display has a built-in advanced power management system designed to conserve battery power. This system will shut down 60 seconds after being placed on a non-moving surface (not hand-held).

When a Blade is not attached to the Display, the video screen and LED battery indicator light will automatically turn off in approximately 20 seconds.

Battery Indicator: The LED battery indicator light in the upper left corner next to the screen is used to indicate the battery status.

When the LED battery indicator light is GREEN the Display has sufficient power to complete a typical laryngoscopy and intubation.

When the LED battery indicator light is FLASHING RED the batteries should be changed before the next use of the Display.

The LED battery indicator light will turn off 20 seconds after the Display is turned on unless the batteries need to be changed.

Housing Material: Polycarbonate and ABS

Packaging: The King Vision Display is provided clean, non-sterile, ready to use in a storage case, ready for first use after the batteries (included) are installed.

SPECIFICATIONS (CONTINUED)

<table>
<thead>
<tr>
<th>Storage and Transport Environment</th>
<th>Operating Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>50°C, 122°F</td>
<td>40°C, 104°F</td>
</tr>
<tr>
<td>-20°C, -4°F</td>
<td>10°C, 50°F</td>
</tr>
<tr>
<td>85%</td>
<td>75%</td>
</tr>
<tr>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>106 kPa, 31.3inHg</td>
<td>106 kPa, 31.3inHg</td>
</tr>
<tr>
<td>50 kPa, 14.77inHg</td>
<td>80 kPa, 23.62inHg</td>
</tr>
</tbody>
</table>

Video-output: The King Vision Display has a unique video-out port (Fig. 1, #6) that can be attached to monitors, video screens, computers or any other device that has a standard analog (RCA Style) video input port. Use only with the King Vision video-output Cable (Part Number KVCABL). The King Vision Display may only be connected to a single UL/IEC 60601-1 certified device that has a current draw limited to 300 mA.
Use of the video-output port will shorten the battery life. It will also shorten the warning time of the LED battery indicator light (less time to change the batteries once the LED begins FLASHING RED.

**Video output Cable Length:** 108 inches, 274 cm

**Shelf life:** The King Vision Display is warranted for one year from date of purchase. The batteries shipped with the Display have a 5-year shelf life from the date of manufacturing.

**Continuous operation:** While designed for short term use to place an endotracheal tube or examine the upper airway, the only practical limitation for duration of use is battery life.

**Electronic Interference:**

The King Vision system has been tested for conformity to applicable standards:

- Other electronic devices may cause interference with the King Vision Display.
- The King Vision Display may interfere with other electronic devices.
- If interference is noted, move the two devices physically apart from each other.

**KING VISION BLADE INFORMATION**

**Endotracheal Tube size:** 6.0 to 8.0 mm I.D. (ONLY for Size 3 Channeled Blade)

**Blade length:** 17cm (excludes handle portion of Blade)

**Minimum mouth opening:** 13 mm (Standard Blade)  
18 mm (Channeled Blade)

**Weight:** 49 grams (Standard Blade)  
58 grams (Channeled Blade)

**Common features King Vision Blades:**

**Illumination Light Source:** LED (white) Note: Do not look directly at the white light as it may cause temporary flash blindness.

**Camera:** CMOS – VGA

**Anti-fog Feature:** Anti-fog coating incorporated on the distal lens – no warm up time needed.

**Materials:** Polycarbonate and ABS

**Packaging:** Supplied in a tray with sealed lid; clean, non-sterile for Single Use only. Do not reprocess or attempt to sterilize the King Vision Blades.

**The Symbols Used with the King Vision Video Laryngoscope:**
The King Vision carries the CE mark.

Type BF equipment per IEC 60601-1.

"Do not reuse"

"Caution"

"Consult Operating Instructions For Use"

On / Off Button.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Laryngoscope. With respect to electric shock, Fire and Mechanical Hazards only in accordance with UL60601-1, IEC60601-1, CAN/CSA C22.2 No 601.1, IEC 60601-2-18, ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1.

Serial Number

Manufacturer’s Catalog Number.

Manufacturer’s Batch Code.

Date of Manufacture.

Manufacturer

Temperature Limitation symbol indicates the upper and lower limits of temperature for this device.

Humidity Limitation symbol indicates upper and lower limits of humidity for this device.

Atmospheric Pressure Symbol indicates upper and lower limits of the atmospheric pressure for this device.

REGULATORY INFORMATION FOR THE KING SYSTEMS VISION DISPLAY

The King Vision Video Laryngoscope components are marked for sale in the European Union with the CE mark.

The King Vision Display is designed for multiple patient uses when properly cleaned and disinfected between patients.

The King Vision Blades are designed for Single Use and cannot be reprocessed or sterilized.
RISK OF REUSE (as required for Single Use devices):
U.S. and International Laws/Regulations require the original device manufacturer to warrant that the product sold is fit for use according to the scope of its Instructions for Use and is capable of being tracked back to its original assembly. If an issue were to arise during use, this requirement allows for the product to be properly tracked and acted upon in accordance with all applicable laws.

Any reuse of a device labeled as a Single Use Device (SUD) invalidates the manufacturer’s requirement to track the product back to its original assembly. As such, any facility that reuses a SUD assumes the role of a manufacturer and must test and verify the suitability of this (reused) device. This includes, but is not limited to, the proper level of cleaning, disinfection and/or sterilization necessary to warrant the reused device’s fitness for use. In the USA, any facility that re-processes a SUD must register with the Food and Drug Administration under Code of Federal Regulations Title 21 as a device manufacturer and abide by all applicable federal and state laws regulating device manufacturers. Outside the USA other laws may apply.

<table>
<thead>
<tr>
<th>Manufactured By:</th>
<th>European Representative</th>
</tr>
</thead>
</table>
| King Systems Corporation  
15011 Herriman Blvd., Noblesville, IN 46060  
1-317-776-6823  
1-800-642-5464  
www.kingsystems.com  
Made in U.S.A. of US and imported parts | MPS  
Medical Product Service GmbH  
Borgasses 20  
35619 Braunfels Germany |

This product is protected by U.S. Patent Nos. D663,026 and D669,172.  
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King Vision® is a trademark of King Systems Corporation.

The King Vision product line meets the requirements of the European Directive 93/42/EEC for medical devices and carries the CE mark.

INFM-78 12/13