CAMx Spectra

Fluorescence Caries Detection Aid System
Part Number G4000

Operator’s Manual
Air Techniques has prepared this document as a guide to the proper use of Spectra Fluorescence Caries Detection Aid System. Review and follow the guidelines included in this Operator’s Manual to ensure that your Spectra gives you the highest level of service.

For product support and information on how to expand Spectra, contact your authorized Air Techniques dealer; call our Technical Support at 1-800-AIR-TECH (1-800-247-8324) or visit the following web site, www.airtechniques.com.

Congratulations on purchasing Spectra, an intra-oral device that aids in the detecting caries. Spectra provides the following benefits:

☐ Aids in the detection of caries.

☐ Facilitates treatment acceptance.

☐ Motivates the patient to carry out a professional tooth cleaning.

☐ Saves images so that patient oral hygiene may be tracked over time.

☐ Spectra can be quickly detached and easily carried between patient operatories.

☐ Ideal complement to an X-ray imaging system for patient care.

This manual covers the installation, operation and maintenance of:

Spectra Fluorescence Caries Detection Aid System, part number G4000
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GENERAL SAFETY

This equipment has been designed to minimize exposure of personnel to hazards. While Spectra is designed for safe operation, certain precautions must be observed. Not complying with the instructions specified in this manual while using Spectra may result in permanent failure of the unit.

KNOWLEDGE OF WARNINGS AND CAUTIONS

Users must exercise every precaution to ensure personnel safety, and be familiar with the warnings and cautions presented throughout this manual and summarized below.

**Warnings.** Alerts user to pay special attention to anything that could injure or kill personnel.

- Due to light emitting diodes (LED) intensity and wavelength, users and patients should not look directly into the blue-violet light from the Spectra Handpiece.
- Exposing Spectra to rain or moisture may pose the risk of electrical shock or fire.
- Unplug the system components from power before cleaning.
- Install the distance spacer snuggly on Spectra to prevent any potential choking hazard.

**Cautions.** Draws special attention to anything that could damage equipment or cause the loss of data.

- Federal law restricts this device to sale by or on the order of a dentist or licensed practitioner. This device should be used only under the continued supervision of a dentist or licensed practitioner.
- There are no user-serviceable parts inside. Servicing should be performed by qualified dealer service representatives only.
- Connecting any device to Spectra that does not meet the equivalent safety requirements of the system may reduce the safety effectiveness of the device.
- Do not autoclave the Camera Handpiece.
- Do not spray liquids directly on Spectra or the cable.
- Do not immerse the Camera Handpiece in liquid of any kind.
- Do not allow liquids to run into internal circuitry.
- Cleaning products containing the ingredients listed below are prohibited for use with Spectra. These chemicals can cause damage to the plastic parts used on the camera body.

- Ammonia
- CaviCide™
- CaviWipes™
- Ethanol
- Iodine solutions
- Methyl Ethyl Ketone
- Ammonium Chloride
- CaviCide1™
- Denatured alcohol
- Ethylene Glycol Monobutyl Ether
- Isopropyl alcohol (higher than 70%)
- Opti-Cide³®
- Benzene
- CaviWipes™
- DisCide® Ultra
- Glutaraldehyde
- Lysol®
- Phenol based compounds

CaviCide™, CaviCide1™, CaviWipes™, CaviWipes1™ are trademarks of Metrex. • DisCide® is a registered trademark of Palmero Health Care.

Lysol® is a registered trademark of Reckitt Benckiser. • Opti-Cide³® is a registered trademark of Micro-Scientific

**Contraindications.**

- None.
Use of Accessory Equipment.
Spectra is intended to provide a level of safety consistent with the IEC 60601-1 standard for medical equipment. In order to achieve this, Spectra must be used with a computer and any other accessory equipment that complies with the IEC 60950-1 standard for information technology equipment (ITE) and this equipment must be set-up outside the immediate patient environment. Use of ACCESSORIES or cables other than those specified or provided by the manufacturer may result in increased EMISSIONS or decreased IMMUNITY of Spectra.

Do Not Attempt Internal Service.
The interior of the camera is only accessible by removing hardware with tools and should only be opened and serviced by an authorized service technician. Contact your local Air Techniques authorized dealer for service. Failure to heed this directive may result in equipment damage and voiding the warranty.

Markings. The following terms or symbols are used on the serial plate or in this manual to denote information of special importance:

![Symbol](image)

Alerts users to important Operating and Maintenance instructions. Read included documents.

![Symbol](image)

Indicates type BF equipment in accordance with IEC 60601-1

![Symbol](image)

Alerts users that the camera sheath must be used for only one patient and disposed of properly in accordance with local code.

![Symbol](image)

Identifies the name of the manufacturer.
Unpack each component and inspect for physical damage such as scratches, damaged connectors, etc. If any damage is noted, immediately notify your Air Techniques authorized dealer so corrective action can be taken.

Verify that all listed items were received. If any item is missing, notify your Air Techniques authorized dealer. Make sure to save all packaging material in case repackaging and shipment is necessary.

**UNPACKING AND INSPECTION**

**COMPONENT DESCRIPTION**

**Spectra Handpiece** - This lightweight handpiece has a high resolution, auto–exposure CCD sensor that is highly sensitive. Its lens system and LED lamps emit blue–violet light at a wavelength of 405nm, which causes metabolic byproducts from caries producing bacteria to fluoresce. When used with the supplied 10mm distance spacer, the fixed focus lens brings all objects within the area of interest in focus enabling it to aid in the identification of potential carious lesions. Two tactile buttons on the handpiece enable the user to have precise control of Spectra even when rotating the device to access a certain area in the patient’s mouth.

**Camera Sheaths Sample Pack** - Provides a quantity of 50 disposable camera sheaths used as an effective barrier preventing any hazard to the patient.

**10mm Distance Spacer Sample Pack** - Provides a quantity of 10 spacers for use with the Spectra Handpiece. Each spacer maintains an appropriate steady distance between the lens tip and the tooth surface and blocks stray light during examinations. Although the spacers are reusable, each must be sterilized before use (see page 15).

**Spectra Handpiece Cable** - A 10-foot cable that is used to connect the Spectra handpiece to the user’s computer. One end of the cable has a keyed, 5-pin quick disconnect connector for connection to the Spectra handpiece and the other end has a Type A USB connector for connection to a USB port on the user’s computer. This cable carries all power, video and keypad button control signals for the handpiece.

**Spectra Handpiece Holder** - The Spectra Handpiece Holder can be fastened in a convenient location for safe storage of the handpiece when it is not in use.

**Compact Disk** - A CD includes:

1. USB Device Drivers, Demonstration Program and Utilities
2. PDF version of Operator’s Manual
3. Adobe Acrobat Reader
Spectra consists of a Handpiece, a Handpiece Cable and associated accessories. The handpiece, cable, accessories and software may be purchased together under part number G4000. Some of the items may be purchased individually by the part numbers listed on page 22. Spectra, Part Number G4000, includes:

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<th>Description</th>
<th>Qty</th>
<th>Item</th>
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<tr>
<td>Spectra Handpiece (P/N G4100)</td>
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<td>PDF version of Operator’s Manual</td>
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<td>Quick Start Instructions</td>
<td>1</td>
<td><img src="image" alt="Quick Start Instructions" /></td>
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**General Notes.**

- Spectra should only be used with authorized software.
- Observe the usage and storage conditions.
- Spectra is an aid in the detection of caries by providing information that supplements the dentist’s visual observations, patient history, and information from other diagnostic techniques, resulting in an overall treatment determination. The system does not provide a diagnosis. Diagnosis subsequent to the use of Spectra is performed and provided by the dentist.
- Always perform a professional cleaning using a Prophy Brush, powder jet cleaner or other acceptable means to remove any debris, meal deposits, dental tartar, plaque detection agents and preventative materials that can interfere with caries detection.
- All instructions in this manual form an integral part of the unit. Precise observance of these instructions is a pre-condition for use of the unit for the intended purpose and for its correct operation. This manual should be passed on to any future purchaser or operator.
- Safety of the operator as well as trouble-free operation of the unit are only ensured by using original parts made by the manufacturer. Use only those accessories that are specified in the technical documentation or that have been expressly approved and released by the manufacturer for the intended purpose. The manufacturer warrants the safety and functioning of this device only when the user expressly abides by these instructions.
- The manufacturer intends to accept responsibility for the equipment with regard to safety, reliability and proper functioning only if assembly, changes or modifications and repairs have been carried out by an authorized dealer and if the equipment is used in conformity with the instructions contained in this manual.
- The device conforms to the relevant safety standards valid at this time.
- Any reprinting of the technical documentation, in whole or in part, is subject to prior written approval by the manufacturer.

**Incorrect Usage.**

- The operator bears all risks. Any use that is not described in this manual as correct usage is considered incorrect. The manufacturer is not to be held liable for any damage caused as a result of incorrect usage.
Spectra and the compliant imaging software work together to aid in the detection of caries after professional oral cleaning. The light emitting diode (LED) lamps in the handpiece emit blue-violet light at a wavelength of 405nm, which causes sound dental enamel to fluoresce with a green color. Areas containing metabolic by-products (porphyrins) from caries producing bacteria fluoresce with red color when lit by the same blue-violet light. The optics and charged coupled device (CCD) sensor in the handpiece pick up the images containing this fluorescence and convert them to an electrical signal. This signal is sent to the user’s computer via a USB cable. The user can then analyze these images displayed on their computer.

The imaging software provides two modes of operation – detection and analysis. Detection mode is used to view the fluorescence of the occlusal tooth surfaces to quickly identify areas for the user’s examination. Areas containing potential caries will show red coloring whereas sound enamel will show green coloring.

Analysis mode is used to aid in the detection of caries. This is done by making a live inspection of the mouth after the teeth have been cleaned and dried, and then freezing the image in an area of interest for the dental practitioner to evaluate. The imaging software highlights the potential areas of carious lesions found in the frozen image by displaying a color spectrum and numbers as shown below. The images obtained from Spectra combined with the user’s examination of them and other X-ray information can be used to detect caries and formulate the appropriate treatment plan.

**Important:** The colors and numbers on the images from Spectra alone should not be used to determine treatment. They should be analyzed together with visual examination and X-ray information for treatment decisions.

<table>
<thead>
<tr>
<th>Displayed Color</th>
<th>Green → Blue → Red → Orange → Yellow</th>
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<tr>
<td>Displayed Number</td>
<td>1.0 → &gt;3.0</td>
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<tr>
<td>Examine for</td>
<td>Healthy Tooth Use Gold Standard techniques to examine for potential caries.</td>
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**HANDPIECE FUNCTIONS**

Power Button and Cable Connector -

(1) Handpiece Connector  A 5-pin connector socket that accepts connection of the keyed 5-pin quick disconnect end of the Handpiece Cable.

(2) ON/OFF Button  Momentarily press this button to toggle the camera between on and off/standby states.

Keypad Buttons - Each keypad button provides the handpiece fingertip control over the PC streaming video capture software via the Handpiece Cable. The specific functions performed by the keypad buttons depend on having the appropriate software installed on the user’s computer. Typical keypad actions are provided below.

**NOTE:** While operating the system in analysis mode, the imaging software highlights the tooth areas with potential carious lesions on the frozen image.

(3) Top Keypad Button  Momentarily press and release this button to toggle between live and frozen images.

(4) Bottom Keypad Button  Momentarily press and release this button to save a frozen image and to return to a live image. Press and hold the bottom button for at least 3 seconds to toggle the system between detection and analysis modes.
**IMPORTANT:** When operating Spectra connected to a high power (500 mA) USB 2.0 port on a Computer System, the computer must also be loaded with Air Techniques Authorized TWAIN or DirectX 9 compliant streaming video software application such as VISIX. Contact your dealer for available Computer Systems and software options.

**NOTE:** VISIX Imaging Software is fully compatible with Polaris.

**Minimum Computer System Requirements** - The minimum computer system requirements necessary to operate Polaris are listed below.

**Operating System:**
- Windows XP Professional with Service Pack 3 or later for an Intel 32-bit processor;
- Windows 7 Professional, Enterprise, or Ultimate with Service Pack 1 or later for an Intel 32-bit or an Intel 64-bit extended (x64) processor;
- Windows 8.1 Professional or Enterprise for an Intel 32-bit or an Intel 64-bit extended (x64) processor; or
- Windows 10 Pro or Enterprise for an Intel 32-bit or Intel 64-bit extended (x64) processor.

**Imaging Software:** Authorized third-party TWAIN or DirectX 9 compliant software.

**CPU Speed:** Pentium-4, 2 GHz or higher

**System RAM:** 256 MB

**Optical Drive:** CD-ROM Capable

**Monitor:** 800 x 600 resolution or higher

**Video Display:** 16 MB video card with 800 x 600 pixel resolution and 32-bit color

**USB Port:** USB 2.0 High-Speed, High-Power Port

**System Properties.**
If unsure of the operating system version installed, check that it meets the necessary requirements by checking the **System Settings** window as shown below.

The **System Settings** window can also be opened from the **Control Panel** button. Just press the **Start** button and select **Control Panel** and then click the **System** icon.
Installing Spectra is as simple as making the necessary connections of the Spectra Handpiece Cable between a PC and the Spectra Handpiece. An imaging software application authorized by Air Techniques, such as VISIX, must also be installed on the PC. Perform the following procedures to set up Spectra.

**Notes:** A Microsoft® *Driver Not Signed* statement may appear. If it does, click *Continue* to proceed with installation.

**USB Device Driver Installation** - Before connecting Spectra to your computer or attempting to use it for the first time, run the Setup program on the Spectra Drivers and Utilities Disk. This CD contains the necessary device drivers to communicate with the imaging software installed on the user’s computer. Normally, this program runs automatically when the CD is inserted into the drive for the first time. If not, run the setup program located in the root directory of the CD (typically D:\Autorun. exe). The Setup program guides the user through updating the computer library files, which must be completed before Spectra will operate properly. More information can be found in the Installation Instructions and Notes file on the Spectra Drivers and Utilities Disk.

![Warning](image.png) Do not twist or turn the Handpiece Cable connector. The connector is keyed and mates straight on with Camera Handpiece connector.

**Spectra Handpiece Connection** - Connect the Handpiece Cable to the handpiece as follows:

1. Using the black molded connector end of the Handpiece Cable, align the connector key with the keyway of the handpiece connector.
2. Insert straight into the connector of the handpiece until it securely snaps into place.
Important: Use a High Power (500 mA) USB 2.0 Port Only

USB Interface Connection - Connect the USB Type A connector side of the Handpiece Cable to any available USB 2.0 High Speed, high power port on the user supplied Computer System. Always make sure to use the same USB port whenever re-connection of the USB cable is necessary.

A self-powered USB hub can be used to extend the handpiece cable length. Do not use a BUS-powered hub or extension cable.

Handpiece Holder Mounting - The Handpiece Cable is designed to fit in a standard chair-side holder with or without the device attached. The Handpiece Holder Kit included with your unit provides an alternative storage solution. If used, install the holder as follows.

1. Select a flat, clean dry wall surface convenient to where the handpiece is located.
2. Secure the molded mounting bracket to the wall using the two screws provided.
3. Carefully align the channel of the holder with the wall mount bracket.
4. Slide the holder all the way down on the wall mount bracket.
**Disposal Camera Sheath Installation**
Install a new Camera Sheath on the Spectra Handpiece for each patient as follows:

1. Remove the handpiece from the holder.
2. Insert the tip of the handpiece between the second and third layers (between the outer paper and plastic layers) with the window facing towards the paper layer. See A and B.
3. Push the handpiece completely in until the tip is fully inserted into the narrow tip of the sheath.
4. Gently squeeze the tip of the handpiece between the thumb and index finger to ensure that the optically clear area of the sheath is flat against the lens tip. See C.
5. Peel away and discard the top plastic layer and the bottom paper layer. See D.

**NOTE:**
For optimum image clarity, the optically clear section of the camera sheath must be aligned with the camera lens by facing the camera/light source section of the handpiece down toward the paper layer.

---

**Preparing For An Examination** – Prepare for an examination as follows:

1. Perform a professional cleaning of the patient’s teeth using a Prophy Brush, powder jet cleaner or other acceptable means to remove any debris, meal deposits, dental tartar, plaque detection agents and preventative materials that can interfere with caries detection.
2. Remove any residual polishing paste using an air/water syringe.
3. Dry the teeth completely.
4. Install a new Camera Sheath on the handpiece as shown in the section below.
5. Install a sterilized 10mm distance spacer onto the handpiece lens tip by performing the procedure on page 15. This spacer helps to block out stray light and to maintain an appropriate steady distance between the lens tip and the tooth surface to be examined.

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*Spectra should be used with a Camera Sheath covering the handpiece. Make sure to use a new disposable Camera Sheath for each patient.*

*The Camera Sheath must be used for only one patient and disposed of properly in accordance with local code.*
Important: Make sure that a camera sheath is properly installed on the handpiece before installing the 10mm distance spacer.

Note: Steam sterilize the 10mm distance spacer in a gravity steam sterilizer at 121°C for 30 minutes and dry time of 20 minutes before use and handle using gloves. Use a new replacement distance spacer as needed.

10mm Distance Spacer Installation - Install a sterilized 10mm distance spacer on the handpiece as follows:

1. Hold the handpiece with a camera sheath properly installed and insert the handpiece tip into the curved end opening of the 10mm distance spacer.
2. Push the handpiece completely in until the tip is fully inserted into the 10mm distance spacer.
3. Make sure that the 10mm distance spacer is properly aligned with the illuminated tip of the handpiece.

Distance Spacer Installation
CAUTION: Verify that the software is running and correctly configured. Refer to System Check information provided on page 18 as necessary.

Operating Procedure – After preparing for the intended examination as described above, perform the following steps to operate Spectra:

1. Start the imaging software.

WARNING: Eye Safety - Do not look directly into the blue-violet light from the Spectra Handpiece. Do not view the blue-violet light directly or through magnifying glasses or any other enlargement device.

Important: DO NOT rapidly turn the handpiece ON and OFF. Rapid turn ON and turn OFF causes Windows to lock out Spectra for 30 to 60 seconds and inhibit operation.

2. Remove the handpiece from the holder and press the ON/OFF button to activate the camera. Verify that the blue-violet LED lamps turn on and that the computer display shows the high-resolution live video images.

3. Place the handpiece lens window over the area of interest. Allow the distance spacer to rest on the occlusal surface of the tooth. Observe the image on the computer monitor screen.

4. Momentarily press and release the top button on the handpiece to freeze the image. View A below shows a typical frozen image in the detection mode. View B shows a typical frozen image in the analysis mode.

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View A. Detection Mode Frozen Image Display

View B. Analysis Mode Frozen Image Display

Software-Processed Fluorescence Images
5. Press and hold the bottom button for at least 3 seconds to switch to detection or analysis mode.

6. Perform one of the following steps as necessary.
   a. Momentarily press and release the bottom button on the handpiece to save the processed image and return back to a live display.
   b. Press and release the top button momentarily again to return to a live display without saving the image.

7. Repeat steps 3 through 6 as necessary.

8. Press the ON/OFF button to turn the handpiece OFF. Verify that the LED light source extinguish and the device turns OFF. Return the handpiece to the holder.

**Clinical Operation Guidelines.** The user must be aware of the following:

- Very high readings, such as greater than 3.0 (yellow color displayed), may indicate that the teeth are not thoroughly cleaned. Clean, dry and then re-examine.

- False positive caries readings may result from fluorescence occurring from the presence of tartar, food and similar debris lodged in or on the surface of the teeth.

- Spectra may also respond to the fluorescent components of some restorative materials such as composite resins, ceramic restorations, sealants and cements. Final assessment depends on the user’s expertise in examining these sites.

- The colors and numbers displayed by Spectra should be used only as an aid in the detection of caries. The displayed image should be used as a guide for the dental practitioner to examine the identified area(s).
USB Video Diagnostic - If live video is not displayed on the PC monitor of Spectra when the imaging software application is running, there could be a problem with the settings in the software application or with the handpiece. Perform the following USB Video Diagnostic procedure to check that the handpiece is working correctly, the Spectra Handpiece Cable is correctly connected between the handpiece and the computer and the system USB driver files are installed correctly on the PC.

1. Go to the **Start** button and select **All Programs**.

2. Select the **Air Techniques** program option and click on **Camera Demonstration Program** and observe that the Camera Demonstration Program screen opens.

3. Depending on the outcome of the diagnostic, perform one of the following:
   a. If a live image is correctly displayed, exit from the application and make sure that the imaging software application is configured correctly.
   b. If a live image is not displayed, exit from the application and check the handpiece, Spectra Handpiece Cable and USB driver file installation.

4. Reset the driver’s video settings by performing the following:
   a. On the Spectra Demonstration Program screen, click the **Properties** button located on the lower left of the live image screen.
   b. On the Properties screen select the **VIDEO PROC AMP** tab and then click the **DEFAULT** button. The image colors should now be correct. Click **OK** to close the Properties screen and exit from application.
Do not twist or turn the Handpiece Cable connector. The connector is keyed and mates straight on with Camera Handpiece connector.

Whether detaching the handpiece from the Handpiece Cable and using it with additional Spectra Handpiece Cables installed on other computers or moving the complete system (handpiece and cable), Spectra is easily shared among patient operatories.

Refer to the corresponding illustrations and perform the following steps when transporting only the handpiece.

1. Retract the collar of quick disconnect connector and simultaneously pull straight from the handpiece.
2. Release the quick disconnect collar.
3. Store the Handpiece Cable by placing the quick-disconnect collar into the Handpiece Holder.
4. Transport the handpiece to next operatory.
5. Connect the handpiece at new location by aligning the connector key on the cable with the keyway of the mating connector of the handpiece.
6. Insert straight into the handpiece connector until it securely snaps into place.

When transporting the complete system (handpiece and cable) among patient operatories, disconnect the USB connector end of the Handpiece Cable, transport the system and reconnect to the new computer. Make sure that the computer in the new operatory is properly setup and using compliant software.

**CAUTION:** Always handle the handpiece carefully. Do not drop and make sure to protect the optical window from scratches. Do not pull handpiece from a standard chair-side holder. Always lift the handpiece straight up from the holder to avoid damage to the connector.
INSPECTION AND CLEANING

Perform the following inspection and cleaning procedures periodically as a preventive maintenance measure to keep Spectra in optimal condition resulting in trouble-free operation producing crisp, clear images.

Do not attempt any internal service of Spectra components. Contact your local authorized Air Techniques dealer for service. Failure to heed this warning may result in equipment damage and voiding the warranty.

Inspection - Routinely inspect each component of Spectra for possible defects as follows:

1. Camera Handpiece -
   a. Check overall handpiece for chips, cracks or other irregularities.
   b. Check the lens window for debris or spots.
   c. Check the connector socket for damage.

2. Cables and Connectors -
   a. Check cables for damaged or deteriorated insulation kinking or twisting.
   b. Check connectors for loose, bent or missing pins.
   c. Check that the quick-disconnect plug end snaps into handpiece connector to snugly secure the cable to the handpiece.

   • Do not autoclave the Spectra handpiece
   • Do not spray handpiece directly with liquids.
   • Do not rinse or immerse the handpiece in liquids
   • Use care not to allow liquids to run into internal circuitry.
   • Do not wipe the surfaces using prohibited chemicals listed on page 4 as they may degrade the finish.
   • Do not apply excessive pressure when wiping; do not scrub.

CAUTION: Unplug Spectra components before performing cleaning.

The Camera Sheath must be used for only one patient and disposed of properly in accordance with local code.

Surface Cleaning Instructions - Clean the handpiece following each patient use. The cleaning instructions must be followed carefully to prevent damage to the camera housing, and internal components. Cleaning products containing active ingredients listed on page 4 are prohibited for use with Spectra. These chemicals can cause damage to the camera and could void the warranty.

1. Disconnect the USB cable. Remove the Camera Sheath and dispose in accordance with local regulations and clean handpiece as follows.

2. Moisten a cloth with warm water and remove any excessive moisture from the cloth before wiping the handpiece.

3. Wipe outer camera body with the moist cloth to ensure no pooling of water surrounds capture switch, ON/OFF switch or USB connection.

4. Window Lens may be cleaned with a cotton swab which is moistened with alcohol.

5. Air dry handpiece before applying a new Camera Sheath or storing.

6. Steam sterilize the distance spacers in a gravity steam sterilizer at 121°C for 30 minutes and dry time of 20 minutes before use. Handle using gloves. Replace as needed.
Input Power: USB powered device using less than 500 mA at 5 volts DC. No external power supply is required. No mains connection.

Video Outputs: High Speed USB 2.0 Video

Sensor: ¼ Inch CCD

Pixels: 720 H X 576 V

Illumination: 6 Blue-Violet (405 nm) LED lamps

Exposure Control: Automatic

Image: Normal, not mirrored

Imaging Distance: 10mm set by distance spacer

Operating Temperature: 10 to 40°C (50 to 104°F)

Storage Temperature: 0 to 70°C (32 to 158°F)

Humidity: 10 to 90% non-condensing

Compliance -

Device Class: USA - FDA Class II Device, listing D081321

Canada - MDR/Class II

Classifications: Portable, Continuous Operation, Type BF Applied Part no mains connection.

Flammable Atmosphere: Cannot use in the vicinity of flammable anesthetic mixtures of air, oxygen or nitrous oxide.

Water/Particulate Matter Ingress Protection: IP40

Electromagnetic Compatibility Conforms to IEC 60601-1-2 See Appendix A.

### PHYSICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Length</th>
<th>Diameter</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece G4100:</td>
<td>8.8 inches</td>
<td>1.1 inches</td>
<td>2.9 oz.</td>
</tr>
<tr>
<td></td>
<td>(22.35 cm)</td>
<td>(2.79 cm)</td>
<td>(82 g)</td>
</tr>
<tr>
<td>Handpiece Cable G4150</td>
<td>10 feet</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(3.05 m)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The following lists the ordering number and description for accessory components available to maintain and expand Spectra to meet your professional needs. Contact your Air Techniques Dealer for information.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G4000</td>
<td>Complete Spectra System as listed on page 7.</td>
</tr>
</tbody>
</table>

Separately packaged accessory components

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G4010</td>
<td>Spectra Handpiece (P/N G4100)</td>
</tr>
<tr>
<td>G4650</td>
<td>Spectra Handpiece Cable (P/N G4150)</td>
</tr>
<tr>
<td>G4011</td>
<td>Handpiece Holder Kit</td>
</tr>
<tr>
<td>G4640</td>
<td>10mm Distance Spacers, Pack of 25</td>
</tr>
</tbody>
</table>

Replacement Disposable Camera Sheaths for Handpiece

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G5111</td>
<td>Box of 100</td>
</tr>
<tr>
<td>G5110</td>
<td>Box of 500</td>
</tr>
</tbody>
</table>

Imaging Software for Spectra

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D4065</td>
<td>VISIX for Spectra Software</td>
</tr>
<tr>
<td>D4040</td>
<td>VISIX Support Package</td>
</tr>
<tr>
<td>74500</td>
<td>Comprehensive VISIX Imaging Software, 5 licenses</td>
</tr>
</tbody>
</table>

**VISIX imaging software**

Consider VISIX, our comprehensive digital imaging software application, providing seamless integration with all our digital imaging ScanX PSP Systems and Spectra Intraoral Cameras.

**Key Features.**

- Easy to learn.
- Simple to use.
- Acquire, mount, view and store images with just a few mouse clicks.
- Exposure - Our Stop Light Exposure System is a unique indicator to ensure optimum data capture. It helps you acquire great images by monitoring X-ray exposure.
- Viewing - VISIX provides automatic image mounting that is completely customizable.
- Flexibility - VISIX includes a built-in bridging solution to over 35 Practice Management Software titles.

VISIX is the superb software complement for Spectra. Contact your authorized dealer for further information.
Spectra is warranted to be free from defects in material and workmanship from the date of installation for a period of 2 years (24 months).

All part and component returns and replacement equipment under warranty require a Return Materials Authorization (RMA). Warranty returns must be received within three months of the RMA issue date. Items returned without an RMA, or included with other products for which an RMA has been issued, may be returned to the customer at the discretion of Air Techniques, Inc.

Any item returned under warranty will be repaired or replaced at our option at no charge provided that our inspection shall indicate it to have been defective. Air Techniques, Inc. is not liable for indirect or consequential damages or loss of any nature in connection with this equipment. Dealer labor, shipping and handling charges are not covered by this warranty.

Warranty credit will not be applied to product returns that exhibit damage due to shipping, misuse, careless handling or repairs by unauthorized personnel. Credit, or partial credit, will not be issued until products/parts have been received and assessed. Warranty is void if product is installed or serviced by anyone other than an authorized Air Techniques’ dealer or service personnel.

This warranty is in lieu of all other warranties expressed or implied. No representative or person is authorized to assume for us any liability in connection with the sale of our equipment.

ONLINE WARRANTY REGISTRATION

Quickly and easily register Spectra on-line. Just have your product model number and serial number available. Then go to the Air Techniques website, www.airtechniques.com, click the warranty registration link and complete the registration form. This on-line registration ensures a record for the warranty period and helps Air Techniques keep you informed of product updates and other valuable information.
Electromagnetic Compatibility (EMC) Compliance Information
The camera was tested with a UL ITE compliant 100-240VAC 50/60Hz mains powered computer and was found to comply with the IEC 60601-1-2 standard for electromagnetic compatibility. The camera needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

- Portable and mobile RF communications equipment can affect camera operation.
- Use of accessories or cables other than those specified or provided by Air Techniques may result in increased camera emissions and decreased camera immunity.
- The camera should not be used adjacent to or stacked with other equipment that may interfere with proper camera operation.

Manufacturer's Guidance and Declaration - Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td></td>
<td>The camera uses radio-electrical energy only for its internal subsystems. Therefore, it emits very low energy and is not likely to interfere with nearby electronic devices.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td>Group 1</td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td></td>
<td>The camera 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 that the following warning is heeded:</td>
</tr>
<tr>
<td>CISPR 11</td>
<td>Class A</td>
<td><strong>Warning:</strong> This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the camera or shielding the location.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EN 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
## Manufacturer’s Guidance and Declaration - Electromagnetic Immunity

The camera is intended to be used within the electromagnetic environment specified below. The user of the camera should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>± 6kV contact ± 8kV air</td>
<td>± 6kV ± 8kV</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines</td>
<td>± 2kV ± 1kV</td>
<td>Mains power quality should be that of typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV line(s) to line(s) ± 2 kV line(s) to earth</td>
<td>± 1kV N/A</td>
<td>Mains power quality should be that of typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions</td>
<td>&lt;5% Ur (&gt;95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles &lt;5% Ur (&gt;95% dip in Ur) for 5 s</td>
<td>&lt;5% Ur - 10ms 40% Ur - 100ms 70% Ur - 500ms &lt;5% Ur - 5 s</td>
<td>Mains power quality should be that of typical commercial or hospital environment. If the user of the camera requires continuous operation during power mains interruptions in the main power supply, it is recommended that the camera be powered from an uninterruptible power supply providing emergency power.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location within a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**Note:** Ur is the a. c. mains voltage prior to application of the test level.
Manufacturer’s Guidance and Declaration- Electromagnetic Immunity

The camera is intended to be used in the electromagnetic environment specified below. The user of the camera should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
</table>
| Conducted RF   | 3 Vrms 150 kHz to 80 MHz | 3 V | Portable and mobile RF communication equipment should be used no closer to any part of the camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:

\[
 d = 1.16 \sqrt{P} 
\]

| Radiated RF    | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | 80 MHz to 2.5 GHz
\[
 d = \begin{cases} 
 1.16 \sqrt{P} & \text{80 MHz to 800 MHz} \\
 2.33 \sqrt{P} & \text{800 MHz to 2.5 GHz} 
\end{cases} 
\]

where \( P \) is the maximum output power of the transmitter in Watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency b.

Interference can occur nearby devices bearing the following symbol:

Note 1: At 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, AM and FM radio broadcast, and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the camera is used exceeds the applicable RF compliance level above, the camera should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the camera.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Recommended Separation Distances Between the Camera and Portable and Mobile RF Communications Equipment

The camera is intended for use in an electromagnetic environment in which radiated RF interferences are controlled. The user of the camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the camera such as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Maximum assigned output power of the transmitter W</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.116</td>
<td>0.116</td>
<td>0.233</td>
</tr>
<tr>
<td>0.1</td>
<td>0.366</td>
<td>0.366</td>
<td>0.736</td>
</tr>
<tr>
<td>1</td>
<td>1.16</td>
<td>1.16</td>
<td>2.33</td>
</tr>
<tr>
<td>10</td>
<td>3.66 —</td>
<td>3.66—</td>
<td>7.36</td>
</tr>
<tr>
<td>100</td>
<td>11.6 —</td>
<td>11.6 —</td>
<td>23.3</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be established by using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

**Note 1:** At 80 and 800 MHz, the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
For over 50 years, Air Techniques has been a leading innovator and manufacturer of dental products. Our priority is ensuring complete satisfaction by manufacturing reliable products and providing excellent customer and technical support. Whether the need is digital imaging, utility room equipment or merchandise, Air Techniques can provide the solution via our network of authorized professional dealers. Proudly designed, tested and manufactured in the U.S., our products are helping dental professionals take their practices to the next level.

Air Techniques’ family of quality products for the dental professional include:

- **Digital Imaging**
  - Digital Radiography
  - Intraoral Camera
  - Caries Detection Aid
  - Intraoral X-ray
  - Panoramic X-ray
  - Film Processors

- **Utility Room**
  - Dry Vacuums
  - Wet Vacuums
  - Air Compressors
  - Amalgam Separator
  - Utility Accessories
  - Utility Packages

- **Merchandise**
  - Surface Disinfectant
  - Enzymatic Cleaner
  - Hand Sanitizer and Lotion
  - Waterline Cleaner
  - Evacuation System Cleaner
  - Imaging Accessories
  - Chemistry
  - Processor Accessories

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