



## **User's Manual**

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**COGENTIX MEDICAL**

**Stroboscopy Unit**

**STR-5000**

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**NOTE: Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.**

***[www.cogentixmedical.com](http://www.cogentixmedical.com)***

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# How to Use This Manual

This User's Manual contains the recommended procedures for preparing and using the Cogentix Medical **STR-5000 Stroboscopy Unit**. It is intended for physicians and other medical personnel who will come in contact with the unit before, during, and after any patient procedures performed with it. The manual also contains pertinent information on the proper care and handling of the unit. Please read and become familiar with this entire manual before using the unit.

This manual contains the following information:

- The equipment's intended use
- Description of the unit, its components and features
- Complete instructions on preparation, inspection, operation, cleaning, and storage of the unit
- Warning and Caution statements that must be observed by users to ensure patient and user safety

If you are a **first-time user of the STR-5000 Stroboscopy Unit**, Cogentix Medical strongly recommends that you read this manual from beginning to end and become intimately familiar with the unit's features and use.

If you are an **experienced user of the STR-5000 Stroboscopy Unit**, select specific chapters and/or sections that pertain to features and procedures that you are using.

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## Organization of this Manual

Following is a list of the chapters included in this User's Manual. Each chapter's title is listed at the top of all pages after the title page, so that you can quickly access the information you need.

**Chapter 1, Symbols and Terms** – This chapter defines the symbols on the unit and peripheral equipment. There is also a brief list of the terms that are commonly used in the manual.

**Chapter 2, Important Information** – The information in this chapter is a summary of critical Warning and Caution statements in the manual. This information is essential to the safe operation of the unit. Cogentix Medical strongly recommends that this chapter be read thoroughly and completely understood by all users before working with the unit.

**Chapter 3, Equipment and Accessories** – Introduces the **STR-5000 Stroboscopy Unit** and compatible equipment. This chapter includes instrument diagrams, identifies components, and defines their functions.

**Chapter 4, Preparation and Inspection** – This chapter describes how to prepare the unit for use, and the assembly of the system in which the unit operates. The chapter also leads you through a detailed inspection procedure to confirm that the unit is undamaged and working properly before it is used in a procedure.

## How to Use This Manual

**Chapter 5, Menus and Settings** – This chapter details the menus available to the user on the **STR-5000** Stroboscopy Unit. Each menu contains settings related to the unit's functionality.

**Chapter 6, Operating the STR-5000** – This chapter defines how to perform the main functions of the **STR-5000** Stroboscopy Unit.

**Chapter 7, Care and Storage** – This chapter contains important instructions on the proper cleaning and storage of the unit.

**Chapter 8, Troubleshooting** – This chapter discusses potential problems users may encounter while operating the unit and possible causes of the problems. For each problem, one or more corrective actions is suggested.

**Chapter 9, Warranty and Service** – This chapter contains the terms of the Cogentix Medical warranty on the unit, any restrictions that apply and user actions that may void the warranty if taken. This chapter also includes shipping instructions in case the unit must be returned to Cogentix Medical or authorized facility for repair.

**Appendix A** contains the technical specifications for the **STR-5000** Stroboscopy Unit.

**Appendix B** contains electromagnetic compatibility and immunity information.

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## Additional Information

The information in this User's Manual is subject to change without notice. If you have any questions regarding any of the material contained in this manual, or wish to confirm that this is the most-comprehensive information available for this product, please contact your local distributor or Cogentix Medical Customer Service Department at 866 258-2182 (toll-free in U.S.) or (+1) 952-426-6189 (international).

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# 1 Symbols and Terms

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## Symbols

The symbols listed below can be found on the **STR-5000** Stroboscopy Unit and on other components of the system.



Type BF applied part (Safety degree specified by IEC 60601-1)



Serial number of the stroboscopy unit



Power off



Power on



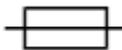
Alerts the user to the presence of important operating, maintenance, and service instructions. Refer to and become familiar with the user's manuals for all equipment used in the procedure



Equipotentiality grounding terminal



The equipment has been designed, tested, and certified as essentially compliant with all applicable European Union (EU) regulations and recommendations



Fuse type and rating



Foot Pedal connection



Microphone connection

## Symbols and Terms

LED

LED Output connection to Video Processor Unit



Do not dispose of as household waste. This product is designated for separate collection at an appropriate collection facility.



The presence of this symbol on the product or packaging indicates that the device is RoHS compliant.



Consult Instructions for Use



Date of Manufacture

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## Terms

The following terms are used throughout this User's Manual:

**"STR-5000"**, **"Stroboscopy Unit"**, and **"Unit"** are all used to refer to the **STR-5000** Stroboscopy Unit.

**Phonation** is the process of producing sound by vibration of the vocal folds in the larynx.

# 2 Important Information

The information in this chapter is essential for the correct and safe operation of the **STR-5000** Stroboscopy Unit. Please read and understand this information before preparing or using the Stroboscopy Unit or any peripheral equipment with which it will be used.

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## Intended Use

The Cogentix Medical **STR-5000** Stroboscopy Unit is intended to be used when performing stroboscopic examination and diagnostic procedures in the larynx, in conjunction with endoscopes, and additional video equipment.

**Do not use the Unit for any purpose other than these intended uses.**

This unit may be used with a Cogentix Medical **DPU-5000** or **DPU-7000 Series** Video Processor. Carefully read and follow the instructions given in this User's Manual as well as those of all other accessory equipment to be used in conjunction with the **STR-5000** Stroboscopy Unit. Failure to thoroughly understand the interoperability of all system components can compromise patient or user safety and/or cause equipment damage.

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## User Qualifications

The Unit should only be used in a medical facility by or under the supervision of a physician trained in laryngoscopy.

Only use the Unit and accessory equipment according to the instructions and under the operating conditions given in this User's Manual. Failure to do so could result in compromised safety, equipment malfunction and/or damage.

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## Cleaning and Disinfection

Only use recommended cleaners and disinfecting solutions when cleaning or disinfecting the **STR-5000** Stroboscopy Unit. Always prepare and use the solutions as recommended by the manufacturer.

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## Maintenance and Service

The **STR-5000** Stroboscopy Unit contains **no** user-serviceable parts (except for fuse replacement); **never** attempt to modify or repair it. Doing so may cause further equipment damage and/or compromise patient safety if the Stroboscopy Unit is subsequently used in a procedure. The Unit may only be serviced/repaired at an authorized Cogentix Medical facility.

## Important Information

In addition to thoroughly inspecting the Unit before each procedure, it should be periodically inspected to determine if there is wear or damage that requires attention.

Refer to Chapter 7, **Care and Storage** for procedures on maintaining the **STR-5000** Stroboscopy Unit.

Refer to Chapter 9, **Warranty and Service** for information on returning the **STR-5000** Stroboscopy Unit to Cogentix Medical or distributor for service.

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## Electromagnetic Compatibility

The **STR-5000** Stroboscopy Unit meets the immunity to interference requirements of IEC 60601-1-2 / EN 60601-1-2, "Electromagnetic Compatibility – Medical Electrical Devices.

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## Signal Words

Information included in this manual to alert users of the possibility of patient injury and/or equipment damage is signified by the Warning and Caution symbols below. Notes are also included in the manual to supply additional helpful information to users.



Alerts the user to situations which, if not avoided, could result in death or serious injury.



Alerts the user to situations which, if not avoided, could result in moderate or minor injury to the user or patient. It is also used to alert the user to conditions and actions that could cause equipment damage.



**NOTE:** Indicates additional helpful information.

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## Safety Precautions

The following precautions should always be exercised when using the **STR-5000** Stroboscopy Unit and all other electromechanical equipment used during the procedure to ensure safety for all involved parties – user(s), patient(s), etc.

### Before Use



Do not allow any liquids on the surface or inside of the unit, other than those approved for cleaning the exterior of the Unit (see cleaning instructions in Chapter 7). This could cause a fire or electric shock hazard. If liquids penetrate the inside of the unit, immediately contact Cogentix Medical and arrange for it to be evaluated by service personnel.

Do not use any accessories that are not in compliance with the equivalent safety requirements of this equipment. Doing so may reduce the operational safety of the system and could cause patient and/or user injury. For all accessories, confirm the safety certifications have been performed in accordance with the appropriate standard (IEC 60601-1-2 / EN 60601-1-2).

Never drop the Unit or subject it to severe impact, as it could compromise its functionality and/or safe operation. Should the Unit be mishandled or dropped, do not use it. Immediately return it to an authorized Cogentix Medical service facility for inspection and repair.

### **CAUTION**

Carefully inspect the Unit and all accessories before use in a procedure, and do not use any equipment that is damaged or excessively worn. Doing so could lead to patient injury and/or further damage to the equipment.

## During Use

### **WARNING**

Do not use the Unit in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide. There is a possibility of fire or explosion.

If any of the components of the Unit malfunction during the procedure, immediately stop using it. Using a Unit that is not functioning properly risks user or patient injury and/or further equipment damage.

Users must never touch the device's interfaces and the patient simultaneously. User and/or patient injury could occur.

### **CAUTION**

Always wear appropriate personal protective equipment when using the unit in a procedure, such as a gown, gloves, and face and eye shields.



# 3 Equipment and Accessories

During the laryngoscopic procedure, the patient makes a sustained vocal sound. The Microphone picks up the sound; the **STR-5000** Stroboscopy Unit measures its frequency and triggers the strobe function of the video processor to enable viewing of the vocal folds on the monitor. The display on the front panel of the Unit will indicate both the measured vocal frequency and sound pressure (volume).

When the Microphone ceases to pick up sound from the patient, the strobe function is disabled and the light remains on continuously. The LEDs on the front panel of the **STR-5000** Stroboscopy Unit will indicate exactly which operating mode is currently active.

The Foot Pedal shipped with the **STR-5000** Stroboscopy Unit gives the user the ability to perform “hands-free” operation of the Unit’s light modes.

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## Inspect the Standard Set



Do not use any equipment that is observed to be damaged or excessively worn. Doing so could lead to patient injury and/or further damage to the equipment.

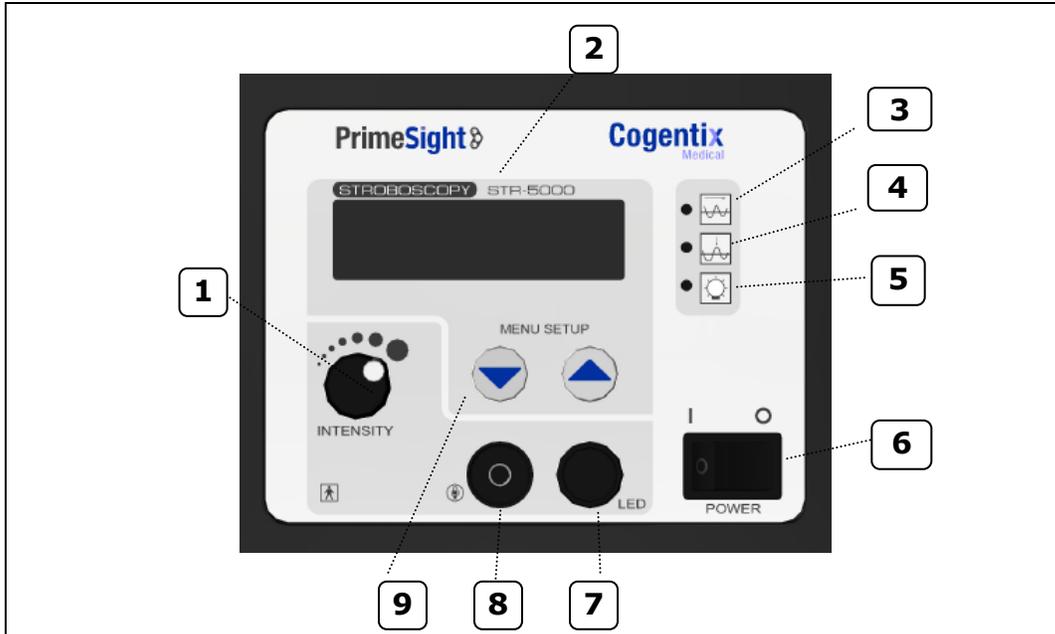
When the Unit is received from Cogentix Medical, immediately confirm that all of the items listed below have been shipped, and inspect them for damage. If any item is missing or damaged, do not use the Unit. Contact Cogentix Medical to obtain a replacement part.

<b>STR-5000 STROBOSCOPY UNIT STANDARD SET</b>	
<b>COGENTIX MEDICAL CATALOG NO.</b>	<b>DESCRIPTION</b>
07-5070	<b>STR-5000 Stroboscopy Unit</b>
07-5071	Microphone for use with laryngoscope
07-5072	Foot Pedal
07-5073	Output Cable (to DPU)
<b>ACCESSORIES</b>	
07-7027	Audio Cable for use with DPU-7000
07-5076	Data Cable for use with DPU-7000
07-5075	SLS-1000 External LED Handpiece
07-5074	Fuses (Type T2.5A/H)
07-3070	Power Cord (North American)
	STR-5000 User’s Manual (this document)

**Table 3-1: STR-5000 Stroboscopy Unit – Standard Set**

## Equipment Diagrams

### STR-5000 Stroboscopy Unit Front Panel

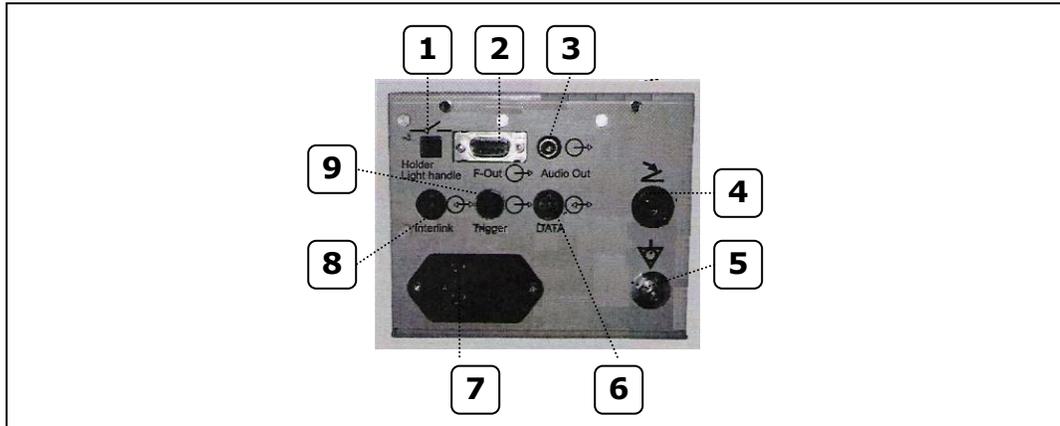


*Figure 3-1: STR-5000 Stroboscopy Unit – Front Panel*

1. **Control Knob:** While operating the Unit, turn this knob to adjust the intensity of the LED light, which in turn changes the brightness of the picture on a connected monitor.
2. **Display:** View and navigate through menus on this screen. The display also shows frequency and volume levels during the procedure, and can show the mean frequency and mean volume after phonation.
3. **“Slow Motion” indicator:** This light is illuminated when the Unit is operating in “Slow Motion” mode with slow motion view of vocal chords. See Chapter 5, **Menus and Settings** on page 13 for details on setting this parameter.
4. **“Locked Phase” indicator:** This light is illuminated when the Unit is operating in “Locked Phase” mode with stop motion view of vocal chords.
5. **“Continuous” indicator:** This light is illuminated when the Unit is operating in “Continuous” mode (i.e., when the light remains on with no strobe effect).
6. **Power Switch:** Press to turn the Unit on and off.
7. **LED Connector:** Connect the male end of the video processor/strobe cable here, and connect the other end to the strobe input connector on the rear panel of the **DPU-5000/7000 Series** Video Processor.
8. **Microphone Connector:** Connect the enclosed microphone’s connector here. For the procedure, clip the microphone to the endoscope or to the patient’s clothing in a location close to their mouth so that sounds can be detected.

9. **Navigation Arrows:** Press these buttons to display the Unit's submenus, navigate through the menus, and set parameters. See Chapter 5, **Menus and Settings**, on page 13 for details on navigating through menus and setting parameters.

### STR-5000 Stroboscopy Unit Rear Panel



**Figure 3-2: STR-5000 Stroboscopy Unit – Rear Panel**

1. **Holder Light Handle:** Not used on Cogentix Medical Videoscopes.
2. **F-Out:** Not used on Cogentix Medical Videoscopes or Video Processors.
3. **Audio Out Connector:** Used for optional audio recording. When used with a DPU-7000 processor, use Audio Cable (07-7027) connected to "Line In" on the DPU to allow for recording of audio.
4. **Foot Pedal Connector:** Connect the enclosed foot pedal to this connector. This will enable "hands-free" operation of the **STR-5000** Stroboscopy Unit.
5. **Potential Equalization Connector:** Used for an equipotential grounding connection if required for the medical facility.
6. **Data:** Used for optional display of parameters (FRQ and SPL) on the DPU-7000 processor only. Connect the Data Cable (07-5076) to the Data port on the rear panel of the DPU-7000 to allow display of strobe exam parameters.
7. **Power Cord Connector / Fuse Access:** Connect to the mains power supply. The Unit's fuses can also be accessed through this connector (see Replacing the Fuses on page 24 for instructions on fuse replacement).
8. **Interlink:** Not used on Cogentix Medical Videoscopes or Video Processors.
9. **Trigger:** Not used on Cogentix Medical Videoscopes or Video Processors.

### Accessories



Do not use any accessories that are not in compliance with the equivalent safety requirements of this equipment. Doing so may reduce the operational safety of the system and could cause patient and/or user injury. For all accessories, confirm the safety certifications have been performed in accordance with the appropriate standard (IEC 60601-1-1 / EN 60601-1-1).

Use of accessories not specified in this manual or sold by Cogentix Medical may result in increased electromagnetic emissions or decreased immunity of the equipment or system.

### Microphone

The Microphone shipped with the **STR-5000** Stroboscopy Unit is positioned near the patient's mouth. It picks up the patient's vocal emanation and transmits it to the Unit, where its frequency ("f") and volume ("SPL") are determined. When these have been determined, the strobe output is activated at the determined frequency to allow visualization of the vocal folds.

### Foot Pedal

In addition to its automatic operation, the included Foot Pedal allows users to control the Unit's light output 'manually'. The position of the pedal controls the three light settings on the **STR-5000** Stroboscopy Unit. For further information on operating the Foot Pedal, see Chapter 6, **Operating the STR-5000 Stroboscopy Unit**.

# 4 Preparation and Inspection

Before using the **STR-5000** Stroboscopy Unit, the various cables and accessories must be connected to it. Only then may the unit be turned on and used in the procedure. Refer to the following procedure and Figures 4-1 through 4-4 below for the proper connections.

**WARNING** If an abnormality is detected when preparing the unit, do not use the equipment. Contact your regional distributor or Cogentix Medical Customer Service.

Thoroughly inspect all accessories to be used in conjunction with the **STR-5000** Stroboscopy Unit. Do not use any equipment that is observed to be damaged. Doing so could cause user or patient injury and/or cause further equipment damage.

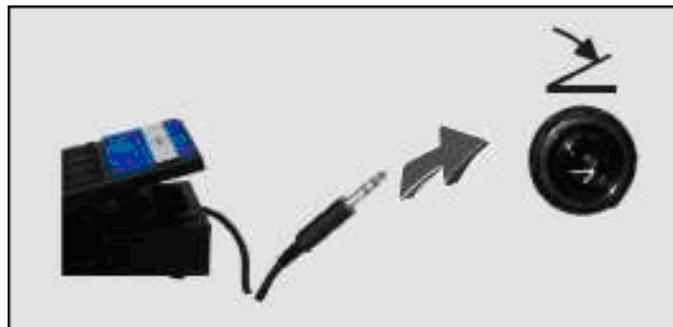
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## Installation and Connection

**CAUTION** Excessive pressure placed on the cables connecting the Unit to ancillary equipment may damage the cables and could affect the light emitted from the **STR-5000** Stroboscopy Unit or the operation of the ancillary devices.

Only use the **STR-5000** Stroboscopy Unit under the ambient conditions specified in Appendix A (page 33). Failure to do so will affect the proper operation of the unit and could cause damage to the unit and/or accessories.

1. Place the **STR-5000** Stroboscopy Unit on a flat, level, stable surface. Make sure that it is placed in a well-ventilated location, in clear view and within easy reach of operators.
2. Connect the Foot Pedal cable to the Foot Pedal Connector on the unit's rear panel (see Figure 4-1).



*Figure 4-1: Connect the Foot Pedal*

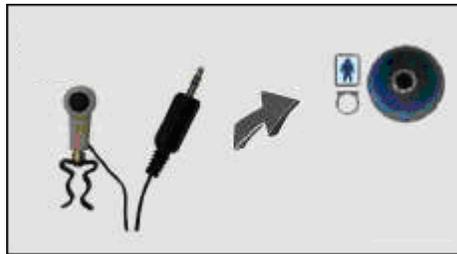
## Preparation and Inspection

3. Insert the video processor/strobe cable into the LED connector on the front panel of the **STR-5000** Stroboscopy Unit, as shown in Figure 4-2. Connect the other end of the cable to the **Strobe** connector on the rear panel of the **DPU-5000 Series** Video Processor. When the STR-5000 is used with a rigid laryngoscope and add-on camera connected to the DPU, the optional LED Handpiece (Cat. # 07-5075) is plugged into the LED connector on the STR-5000 and the LED Handpiece is attached to the light post of the rigid scope.



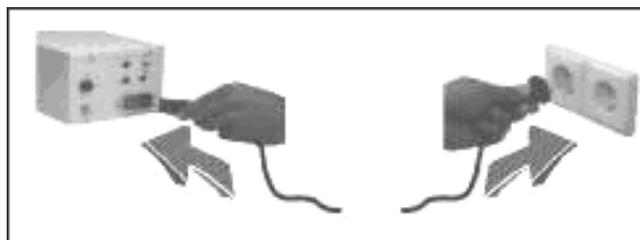
**Figure 4-2: Connect the Video Processor/Strobe Cable**

4. Connect the Microphone to the unit as shown in Figure 4-3. The microphone connector is on the front panel of the **STR-5000** Stroboscopy Unit.



**Figure 4-3: Connect the Microphone**

5. Clip the Microphone on the upper portion of the endoscope's cable close to the control section (handle), or to the patient's clothing in a location close to their mouth.
6. Audio Out and Data connections only for the DPU-7000 Series Video Processors may be made using the Audio Cable (07-7027) and Data Cable (07-5076) to allow for recording of audio and display of strobe information.
7. Finally, connect the Power Cord to both the connector on the rear panel of the Unit and to a wall mains outlet, as shown in Figure 4-4.



**Figure 4-4: Connect the Power Cord**

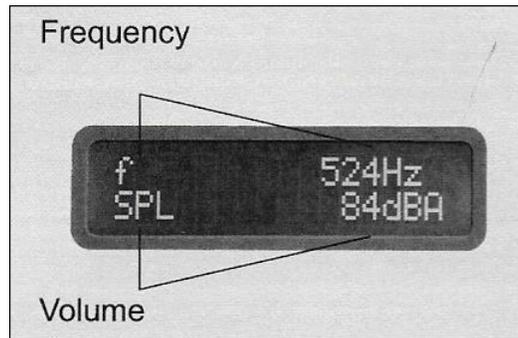
# 5 Menus and Settings

The front-panel display on the **STR-5000** Stroboscopy Unit shows both measured values and menus from which the various settings are made. This chapter will cover the display and all of the menus, which are navigated through and selected using the buttons on the front panel.

---

## Display

Figure 5-1 shows the display of the **STR-5000** Stroboscopy Unit during normal operation. When the microphone has been positioned near the patient's mouth and the patient's vocal emanation is measured, the display output shows both the frequency (f, in hertz) and sound pressure level (SPL) or volume (in decibels).



**Figure 5-1: Frequency/Volume Display During Use**

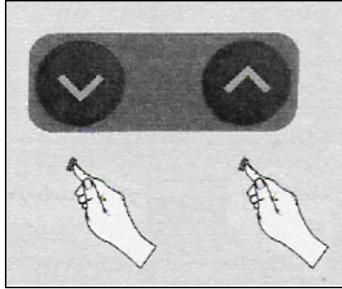
After the procedure is complete, the display shows both the mean frequency and the mean volume measured during the procedure (see Figure 5-2).



**Figure 5-2: Mean Frequency/Volume Display After Procedure**

## Adjusting the Display

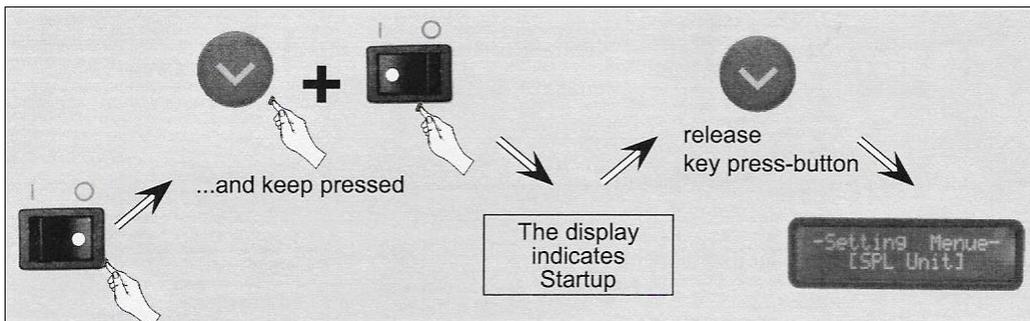
The only adjustment that can be made on the display screen is the contrast, which can either be increased or decreased using the corresponding arrow buttons on the front panel (see Figure 5-3 on page 14). Users can either press the button repeatedly to change the contrast, or simply press and hold the button for continuous adjustment.



**Figure 5-3: Contrast Adjustment Buttons on the Front Panel**

### Using the Setting Menu

Settings and options for the **STR-5000** Stroboscopy Unit's LED Light Source can be accessed via the Setting Menu. From here, the user has access to the six (6) sub-menus that provide information, testing, and operational settings. The full procedure to access the Setting Menu is shown in Figure 5-4 below.



**Figure 5-4: Access the Setting-Menu**

1. If the **STR-5000** Stroboscopy Unit is on, it must be turned off before beginning.
2. Turn on the Unit's Power Switch while pressing and holding the "Down" arrow simultaneously. The display momentarily reads "Startup", then goes blank.
3. Release the "Down" arrow. The display reads "Setting Menu" [SPL Unit]. This is the first sub-menu.
4. To open or close any sub-menu, press the "Up" arrow.
5. To change a selection within a submenu, press the "Down" arrow.
6. To scroll through all available menus while not in a sub-menu, press the "Down" arrow.
7. After scrolling through all menus and making all necessary setting changes, you will see the last submenu [Exit]. To exit, press the "Up" arrow. Then you will see the message "Please switch off and on again." The **STR-5000** Stroboscopy Unit must be restarted for the setting changes to be stored.

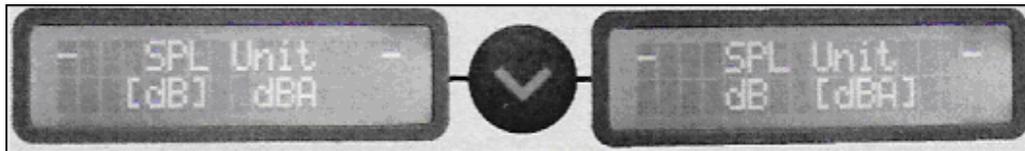
## Sub-Menus

The six sub-menus accessible from the Setting Menu are outlined below. The name of each sub-menu appears below the "Setting Menu" title on the display:

### SPL Unit

Use this sub-menu to select the sound-pressure level (SPL) "Unit" that will be measured and displayed on the **STR-5000** Stroboscopy Unit; either in decibels (dB) or in absolute decibels (dBA).

Pressing the "Up" arrow from the initial Setting Menu opens the unit selection options, shown in Figure 5-5.



**Figure 5-5: SPL Unit Selections**

To retain the dB unit of sound pressure, press and hold the "Up" arrow. To change to the dBA unit, first press the "Down" arrow. The other unit will be bracketed. Then, press and hold down the "Up" arrow to enter the selection. The display returns to the initial page of the SPL Unit menu; press the "Down" arrow to scroll through the remaining menus.

### Slow Motion

On this menu, you can select the frequency of strobe to create a "slow motion" effect while viewing the patient's vocal folds, rather than the real-time effect automatically created by the unit. There are three frequencies that can be selected: 0.5 oscillations/second; 1 oscillation/second; and 2 oscillations/second.

From the initial Setting Menu display, press the "Down" arrow once to access the Slow Motion menu shown in Figure 5-6.



**Figure 5-6: Slow Motion Menu**

The default selection of 1 oscillation/second is bracketed. Press the "Down" arrow to cycle through the three options, and press the "Up" arrow to enter the selection. The display will return to the initial Slow Motion screen. Press the "Down" arrow to continue scrolling through the menus.

### Self-Test

From this menu, the user triggers a test of the **STR-5000** Stroboscopy Unit's internal software. Pressing the "Up" button results in the display shown in Figure 5-7, which asks the user to confirm whether or not the test is to be performed. Press the "Up" button to start the test, or press the "Down" button to highlight "No" on the display if you do not wish to perform the test.



**Figure 5-7: Confirm Selftest**

During the test, the display appears as it does when a procedure is underway. The display will indicate when the test is over by displaying the message shown in Figure 5-8. At this point, press the "Up" arrow to return to the first Selftest display, and then press the "Down" arrow to access the remaining menus.



**Figure 5-8: Display After Successful Selftest**

### CAUTION

If an error is detected or the message shown in Figure 5-8 is not displayed, **do not use** the **STR-5000** Stroboscopy Unit. Contact Cogentix Medical to arrange for servicing of the Unit.

### Version

This menu is informational in nature. Pressing the "Up" arrow after selecting this menu results in the display shown in Figure 5-9 below. This is the date and time that the latest version of the software was updated in the Unit. Press the "Up" arrow to exit the Version menu, and then press the "Down" arrow to continue accessing menus.



**NOTE:** This information also appears for a brief period when the Unit is turned on.



**Figure 5-9: Date/Time of Latest Software Version Update**

### Audio Out Gain

The gain or amplification of the audio out signal from the **STR-5000** to a recording device may be adjusted in steps of 3dB over a range of 0dB (minimal) to 30dB (maximum). The standard output level for most recording is 0dB but may be increased if the sound is too weak.



*Figure 5-10: Audio Out Gain*

### Calibration

The Foot Pedal supplied with the **STR-5000** Stroboscopy Unit is already calibrated for proper functioning with the Unit. However, if a different Foot Pedal is used, it must be calibrated before it is used. Figure 5-11 shows the two-step calibration procedure.



*Figure 5-11: Foot Pedal Calibration Steps*

From the "Setting Menu – Calibration" screen, press the "Up" arrow. You'll be asked to place the Foot Pedal in the "heel down" position. Press the "Up" arrow again when this has been done, and you will be instructed to place the pedal in the "tip down" or "toe down" position. Press the "Up" arrow once more to complete the calibration of the Foot Pedal.

### Exit

Pressing the "Up" arrow when "Setting Menu – [Exit]" is displayed indicates to the **STR-5000** Stroboscopy Unit that all settings have been made. To ensure that the settings are properly stored, the Unit must be turned off and then on again.



# 6 Operating the STR-5000 Stroboscopy Unit

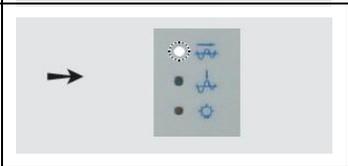
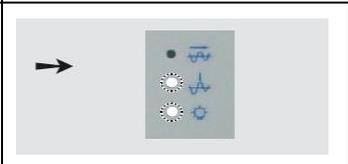
During a laryngoscopic procedure that employs the **STR-5000** Stroboscopy Unit, the “strobe-light” effect that it creates allows the physician to see what is essentially a still image of the patient’s vocal folds.

The frequency of the light pulses applied by the Unit is determined by the information fed into the **STR-5000** Stroboscopy Unit from the Microphone. When the endoscope is in position to view the larynx, the patient makes a vocal tone. The Microphone picks up the sound, calculates its frequency and volume, and generates strobe light output equal to the vocal frequency. When viewed on a monitor or other video source, this synchronization of the frequency between the light and the patient’s voice creates what appears to be a still image of the patient’s vocal folds. When the Microphone does not pick up any sound, the **STR-5000** Stroboscopy Unit does not apply a stroboscopic output; the light remains on according to the last detected pitch.

Alternatively, a “slow-motion” image can be produced. This operating mode on the **STR-5000** Stroboscopy Unit modifies the frequency of the light pulses so that the patient’s vocal folds appear to be moving in slow motion. This allows the motion of the vocal folds to be viewed in greater detail. A third operating mode results in continuous light irrespective of the vocal tones.

## Using the Foot Pedal

The three operating modes of the **STR-5000** Stroboscopy Unit are managed with the Foot Pedal, as shown in Figure 6-1.

	Continuous Light	
	Slow Motion	
	Locked mode of vocal cord oscillations	

**Figure 6-1: Foot Pedal Positions and Operating Modes**

## Operating the STR-5000 Stroboscopy Unit

When the Foot Pedal is in the “heel down” position, shown at the top of Figure 6-1, the **STR-5000** Stroboscopy Unit is in “Continuous” mode; it is not operating in either strobe mode. The lowest of the three LEDs on the Unit’s front panel is illuminated when the unit is in this mode.

Moving the Foot Pedal into the “Tip Down” or “Toe Down” position activates the Unit’s “Slow Motion” mode. This is shown in the middle of Figure 6-1. In this mode, only the top, “Slow Motion” LED on the front panel is illuminated.

The common “locked” operating mode of the **STR-5000** Stroboscopy Unit is activated by placing the Foot Pedal midway between the “heel-down” and “tip-down” positions. While the **STR-5000** Stroboscopy Unit is operating in this mode, the center LED and the bottom “Continuous” LED are lit.

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### Image Brightness Control

When viewing the image, use the Control Knob on the front panel of the **STR-5000** Stroboscopy Unit to set the image’s brightness to your preference.

When the Unit is first turned on, turn the brightness Control Knob all the way clockwise to maximize the brightness. Then, slowly turn the Control Knob to the left until the image on the monitor appears as desired.

During normal operation, turn the Control Knob to adjust the brightness of the LED. Turn the Control Knob to the right to increase the LED brightness, and turn it to the left to decrease the brightness. **Do not** adjust the illumination level with the Light Intensity controls on the **DPU-5000/7000 Series** Video Processor.



**NOTE:** It is possible that increasing the brightness will cause the image to over-saturate. In general, the darker the lighting, the clearer the picture will be.

# 7 Care and Storage

**CAUTION** The **STR-5000** Stroboscopy Unit and accessories cannot be autoclaved, steam-sterilized, or subjected to immersion. Any of these can cause severe damage.

Always disconnect the power cable before cleaning/disinfecting any component of the Unit. Failure to do so may result in injury or damage to the equipment.

When the endoscopic procedure is complete, the system including the **STR-5000** Stroboscopy Unit must be disassembled and reprocessed. Because the Unit does not come in contact with the patient, and because of its sensitive internal electronics, only surface cleaning and disinfecting may be used on the **STR-5000** Stroboscopy Unit.

Follow the procedures given in this chapter for disassembling, inspecting and reprocessing the **STR-5000** Stroboscopy Unit and its components.

---

## After Use

Refer to the operating instructions supplied with all components in the endoscopic system to establish the correct order in which electronic components should be turned off. Some peripheral devices must be turned off first to avoid compromising their operation.

Wipe all external, non-display surfaces clean with gauze slightly dampened with alcohol.

Gently wipe the display with an appropriate screen cleaner.

Make sure that the connector interfaces and ventilation ports do not get wet or splashed with liquids.

---

## Routine Periodic Inspection

Although the **STR-5000** Stroboscopy Unit has no user-serviceable parts (except fuse replacement), certain inspection steps should be performed periodically, in addition to those performed before and/or after procedures, to detect problems that could affect the Unit's operation. Among the steps in such an inspection procedure:

- Confirm that the Unit's power plugs and signal connections fit securely.
- Confirm that the switches and lights on the Unit are working properly.

## Care and Storage

- Confirm that all cables used in conjunction with the Unit are in good condition and have not sustained any damage beyond normal wear and tear.
- Confirm that the Unit is in good working condition immediately following transportation or routine cleaning/disinfection.

Cogentix Medical recommends that users should not allow unauthorized facilities to perform repairs or service on the **STR-5000** Stroboscopy Unit. Repair by any party other than Cogentix Medical will void the warranty.

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## Cleaning and Surface Disinfection

**CAUTION** Failure to properly clean the **STR-5000** Stroboscopy Unit may render disinfection ineffective.

Do not allow excessive moisture or liquids to have direct contact with the **STR-5000** Stroboscopy Unit.

Do not use cleaning/disinfecting agents that are not permitted for use with plastics. For example, ammonia, acetone, or salty acids (HCl).

Do not use cleaning/disinfecting agents on the display that are not designed for use on monitor displays.



**NOTE:** The compositions of plastics, varnishes and colors are constantly being modified. Before cleaning or disinfecting the **STR-5000** Stroboscopy Unit, perform a test with the solution on a non-visible area of the Unit (the underside, for example).

## Cleaning and Disinfection Materials

### ***For Cleaning***

- An approved surface detergent
- 70% Alcohol
- Soft Material (e.g., gauze 4 x 4, lint-free cloth, etc.)

### ***For Surface Disinfection***

- Surface disinfectant compatible with electronic devices

### Cleaning the STR-5000 Stroboscopy Unit

The **STR-5000** Stroboscopy Unit, Microphone, Foot Pedal, and cables should only be cleaned with agents designed for the external cleaning of electrical equipment, and these agents should only be used according to the manufacturer's instructions.

1. Gently pat down and wipe the Unit with a soft material (gauze 4 x 4 or lint-free cloth) to remove any gross debris.
2. Dry all external surfaces of the Unit.

### Surface Disinfection of the STR-5000 Stroboscopy Unit

The **STR-5000** Stroboscopy Unit should only be disinfected with agents designed for external disinfection of electrical equipment, and these agents should only be used according to the manufacturer's instructions.

1. Clean the surfaces of the Unit as described above.
2. Carefully wipe the surfaces of the Unit with a surface disinfectant compatible with electrical equipment. Do not allow liquids to get into or splash on electrical connections.
3. Allow the Unit to remain exposed to the disinfectant for the period of time recommended by the disinfectant manufacturer.
4. Carefully wipe the Unit with 70% alcohol and wipe all external surfaces with soft material (gauze 4 x 4 or lint-free cloth) until they are completely dry.
5. Confirm that the Unit has no disinfectant solution residues on it before using it again.

### Sterilizing the STR-5000 Stroboscopy Unit

The processor cannot be sterilized using traditional methods. For more information, contact your Cogentix Medical representative.

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## Maintenance and Repair

Periodically the **STR-5000** Stroboscopy Unit, **DPU-5000/7000 Series** Digital Video Processor, and accessories should be inspected for operation and safety. Although not essential, preventative maintenance can identify potential problems before they happen, ensuring that the equipment has a reliable and long operating life.

Defective items must be serviced and repaired exclusively by persons authorized by Cogentix Medical. All repair work shall use original manufacturer's parts only.

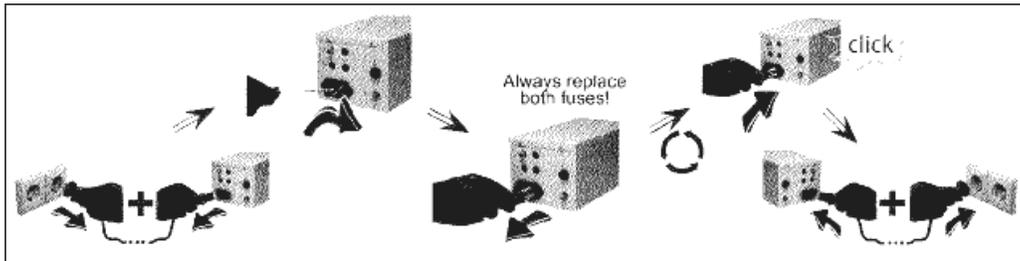
Users should never attempt to alter or modify the equipment. Repairs should only be performed by an authorized Cogentix Medical service facility.

### Replacing the Fuses

**WARNING**

Never change the fuses on the **STR-5000** Stroboscopy Unit while its power is on or when it is connected to a wall mains outlet. Doing so risks electric shock to the person changing the fuses.

If the **STR-5000** Stroboscopy Unit blows a fuse, it will be necessary to replace both fuses. The fuses are located behind the Power Cord Connector on the rear panel. The procedure is shown in Figure 7-1, followed by the steps in the procedure.



**Figure 7-1: Fuse Replacement Steps**

1. Turn off the power to the **STR-5000** Stroboscopy Unit. Disconnect the power cord from both the unit and the wall mains outlet.
2. There is a small tab inside the Power Cord Connector. Use a screwdriver or similar object to release the tab and pull out the fuse holder.
3. Discard both fuses in the fuse holder and install two new fuses of Type T2.5AH.
4. Reinsert the fuse holder into the rear panel of the unit. Push it in until it clicks.
5. The power cord can now be reconnected both to the unit and to the wall mains outlet.

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### Storage

#### **CAUTION**

The **STR-5000** Stroboscopy Unit should **NEVER** be stored in areas where it could be exposed to liquids or environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect its operation.

The **STR-5000** Stroboscopy Unit should **NEVER** be stored in the presence of flammable or explosive gases or chemicals.

Only store the **STR-5000** Stroboscopy Unit under the ambient conditions specified in the Appendix. Failure to do so will affect the proper operation of the Unit and could cause damage.

If the **STR-5000** Stroboscopy Unit is not expected to be used for a prolonged period of time, disconnect all cables and store it in a clean, dry area away from direct sunlight, excessive heat, and liquids.

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### Disposal

When disposing of the equipment, do so in accordance with your local regulations. Contact your local Cogentix Medical representative or service facility if you require further information.



# 8 Troubleshooting

The tables in this chapter are intended to help users diagnose problems that may occur during operation of the Unit. It includes some of the problems that could arise during operation, and suggested corrective actions.

If the suggested corrective action does not solve the problem, contact your local distributor or Cogentix Medical Customer Service Department at 866 258-2182 (toll-free in U.S.) or (+1) 952 426-6189 (International).

**CAUTION** If the problem persists even after the corrective action has been taken, or a problem occurs that is not covered in the tables, do not use the Unit. Contact Cogentix Medical for repairs using the information given in Chapter 9, **Warranty and Service**.

PROBLEM	POSSIBLE CAUSE(S)	CORRECTIVE ACTION
<b>Light source doesn't go on.</b>	<ul style="list-style-type: none"> <li>Power cable is not connected properly.</li> <li>A fuse has blown or is defective.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Confirm that the power cable is connected properly both on the Unit's rear panel and at the wall mains outlet.</li> <li>⇒ Check the Unit's fuses, replace as necessary.</li> </ul>
<b>Display screen is illegible.</b>	<ul style="list-style-type: none"> <li>Contrast is not set properly.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Adjust the contrast by pressing the up or down arrow buttons on the Unit's front panel.</li> </ul>
<b>Image is blurred.</b>	<ul style="list-style-type: none"> <li>Video processor is not switched to strobe mode.</li> <li>Brightness is not set properly.</li> <li>The foot pedal is incorrectly set for continuous lighting.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Use keyboard or endoscope activation button to initiate strobe mode.</li> <li>⇒ Adjust the brightness of the Unit using the Control Knob on the <b>STR-5000</b> front panel.</li> <li>⇒ Reset the foot pedal for "slow motion" or "locked mode" lighting.</li> </ul>
<b>The acoustic signal is not being picked up properly.</b>	<ul style="list-style-type: none"> <li>The microphone is not connected properly.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Confirm that the microphone is connected and operating properly. Also confirm that the microphone is close enough to the acoustic source and is correctly oriented.</li> </ul>

**Table 8-1: Troubleshooting**

## Troubleshooting

PROBLEM	POSSIBLE CAUSE(S)	CORRECTIVE ACTION
<b>Image is too dark.</b>	<ul style="list-style-type: none"> <li>Brightness is too low.</li> <li>Strobe mode is activated while the <b>STR-5000</b> is not connected to the <b>DPU-5000/7000 Series</b> Digital Video Processor, or is turned off.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Use the Control Knob to increase the brightness.</li> <li>⇒ Turn Strobe mode off. Confirm that the <b>STR-5000</b> is properly connected to the <b>DPU-5000/7000 Series</b> Digital Video Processor and that the <b>STR-5000</b> is turned on. Then activate the Strobe mode.</li> </ul>
<b>Foot pedal does not work.</b>	<ul style="list-style-type: none"> <li>Foot pedal is not connected properly.</li> <li>Foot pedal is not calibrated properly.</li> </ul>	<ul style="list-style-type: none"> <li>⇒ Connect the foot pedal properly. Turn off the Unit, wait 5 seconds, and then turn the Unit on again.</li> <li>⇒ Calibrate the foot pedal using the Calibration sub-menu.</li> </ul>

**Table 8-1: Troubleshooting (cont'd)**

# 9 Warranty and Service

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## Warranty Information



**NOTE: Alterations or repairs performed by persons not authorized by Cogentix Medical will void this warranty.**

Cogentix Medical is not liable for any damages to the **STR-5000** Stroboscopy Unit resulting from the following:

- Misuse
- Negligence
- Failure to correctly follow the instructions given in this User's Manual
- The use of accessories not specified or recommended by Cogentix Medical for use with the **STR-5000 Stroboscopy Unit**
- Improper cleaning or storage

The warranty defined herein shall apply only to the original buyer. In no event shall Cogentix Medical be liable for anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of this equipment.

Cogentix Medical sells many of its products through regional distributors. Before sending equipment to Cogentix Medical, contact your regional distributor for repair/return procedures.

Alterations or repairs performed by persons not authorized by Cogentix Medical will void this warranty.

Cogentix Medical warrants that the **STR-5000** Stroboscopy Unit and its accessories will be free from defects in materials and workmanship **for a period of one year from the date of the invoice**. Replacement parts are warranted **for a period of ninety (90) days from the date of the invoice**.

All non-warranty repairs will be warranted to be free from defects in materials and workmanship **for a period of ninety (90) days from the date of the invoice**.

Upon receipt of a **STR-5000** Stroboscopy Unit for repair, Cogentix Medical will evaluate the instrument and make the final decision as to the warranty status.

**The above warranties are in lieu of all other warranties, either expressed or implied, including warranties of fitness or merchantability.**

### Cogentix Medical Service Information

The **STR-5000** Stroboscopy Unit is serviced at authorized Cogentix Medical facilities only. Use the following procedure to expedite returned goods for repair or replacement:

1. Telephone your regional distributor or Cogentix Medical Customer Service (Monday through Friday from 8:00 AM to 7:00 PM EST).
  - USA customers call 866-258-2182 (toll free in U.S.)
  - International customers call (+1) 952-426-6189 for Cogentix Medical Customer Service or call your regional distributor.
  - Fax 866 255-4522 (toll free in U.S.)
  - Fax 952 426-6199 (international)
  - Email: [customercare@kogentixmedical.com](mailto:customercare@kogentixmedical.com)
2. Provide a detailed description of the problem.
3. If troubleshooting cannot solve the problem, a Returned Goods Authorization (RGA) number will be issued.
4. Complete an Incident Report Form and send it to Cogentix Medical along with the returned goods.

### Shipping to Cogentix Medical or Distributor



If the **STR-5000** Stroboscopy Unit has been used in a clinical setting, **disinfect** all system components before shipping as described in Chapter 7, **Care and Storage**. Shipping contaminated equipment could present an acute infection-control risk for those handling the Unit, both during shipping and at Cogentix Medical or authorized facility.

If the **STR-5000 Series** Stroboscopy Unit has been used in a clinical setting but cannot be disinfected before shipping, place a red biohazard label on the shipping container to indicate that the contents are contaminated, in accordance with OSHA standards 29 CFR 1910.1030.

Observe the following precautions before shipping the **STR-5000** Stroboscopy Unit:

The **STR-5000** Stroboscopy Unit or any other Cogentix Medical equipment must be shipped in the original box with the original protective padding to prevent damage during shipment. If the original packaging is not available at the time of shipping, contact your regional distributor or Cogentix Medical Customer Service Dept. to obtain replacement packaging. **The customer will be responsible for the cost of all replacement materials.**

Regardless of warranty status, all shipping charges to and from an authorized Cogentix Medical facility are the responsibility of the customer.



**NOTE:** The customer will be contacted and advised of the estimated repair costs. Repairs will not begin on any equipment until authorization or a purchase order has been issued indicating approval of the charges.



# Appendix A – Specifications

## STR-5000 Stroboscopy Unit Specifications

<b>Operating voltage</b>	100 – 240 V, 50/60 Hz
<b>Power consumption (max.)</b>	0.3 A
<b>Input power</b>	30 VA
<b>Flash frequency</b>	70 - 1000 Hz, +/-1 Hz
<b>Sound level range</b>	70 - 125 dB, +/-1 dB
<b>Power cord</b>	2m length, grounding contact plug, non-heating
<b>Microphone</b>	Airborne sound microphone, impact sound adaptor optional
<b>Modes of operation</b>	Continuous lighting; slow motion 0.5 – 2 Hz; freeze image 0°- 400° phase shifting, adjustable via foot pedal
<b>Operating time</b>	Continuous operation
<b>Enclosure leakage current</b>	0.1 mA NC
<b>Patient leakage current (max.)</b>	0.1 mA NC
<b>Earth leakage current (max.)</b>	0.5 mA NC
<b>Heat release</b>	30 Joule/sec maximum
<b>Noise emission</b>	None
<b>Ambient conditions for Transport and Storage</b>	-30° to 50° C, 5 – 90% humidity (without condensation), atmospheric pressure 700 - 1060 hPa
<b>Ambient conditions for Operation</b>	5° to 35° C, 20 – 80% humidity (without condensation), atmospheric pressure 700 - 1060 hPa
<b>Dimensions (H x W x D)</b>	118mm x 139mm x 280mm
<b>Weight</b>	5 kg
<b>Regular safety-technical controls</b>	After 12 months
<b>Degree of protection</b>	BF
<b>Protection category</b>	P20
<b>UMDNS-Code</b>	12-346



# Appendix B

## Electromagnetic Compatibility Information

The **STR-5000** Stroboscopy Unit meets the immunity to interference requirements of IEC 60601-1-2 / EN 60601-1-2, "Electromagnetic Compatibility" – Medical Electrical Devices.

Medical electrical equipment is subject to special precautions with regard to EMC and must be installed according to following EMC notes:

- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters or other cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.
- The device may not be used directly next to other devices or stacked upon other devices. If operation next to or stacked upon other devices is necessary, please watch the device to check its intended operation in this arrangement.

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### Emissions

The **STR-5000** Stroboscopy Unit is intended for use in the electromagnetic environments specified below. Users should ensure that it is only used in such environments.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF Emissions CISPR 11	Group 1	The <b>STR-5000</b> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The <b>STR-5000</b> is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Not Applicable	
Flicker IEC 61000-3-3	Not Applicable	

**Table B-1: Electromagnetic Emissions Compatibility**

## Electromagnetic Compatibility Information

### Immunity

The **STR-5000** Stroboscopy Unit is intended for use in the electromagnetic environments specified below. Users should ensure that it is only used in such environments.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If the floors are synthetic, the relative humidity should be 30% or higher.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV for mains cables	Mains power quality should be equivalent to that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV symmetric ± 2 kV symmetric	Mains power quality should be equivalent to that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be equivalent to that of a typical commercial or hospital environment.
Voltage Dips / Dropouts IEC 61000-4-11	< 5 % $U_T$ (> 95 % Dip of the $U_T$ ) for 0.5 Cycle  40 % $U_T$ (60 % Dip of the $U_T$ ) for 5 Cycles  70 % $U_T$ (30 % Dip of the $U_T$ ) for 25 Cycles  < 5 % $U_T$ (> 95 % Dip of the $U_T$ ) for 5 seconds	< 5 % $U_T$ (> 95 % Dip of the $U_T$ ) for 0.5 Cycle  40 % $U_T$ (60 % Dip of the $U_T$ ) for 5 Cycles  70 % $U_T$ (30 % Dip of the $U_T$ ) for 25 Cycles  < 5 % $U_T$ (> 95 % Dip of the $U_T$ ) for 5 seconds	Mains power quality should be equivalent to that of a typical commercial or hospital environment. If users require continuous operation even during power interruptions, connect the <b>STR-5000</b> to an uninterruptible power supply (UPS) or external battery.
<b>NOTE:</b> $U_T$ is the mains alternating current prior to application of the test levels.			

**Table B-2: Electromagnetic Immunity Compatibility**

## Electromagnetic Compatibility Information

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3V <sub>eff</sub> 150 kHz to 80 MHz	3 V <sub>eff</sub> 150 kHz to 80 MHz 80% AM 1 kHz	Portable and mobile communications equipment, including cables, should be separated from the <b>STR-5000</b> by no less than the distances calculated and listed below.  <b>Recommended distances:</b> $D = 1.17 \sqrt{P}$ $D = 1.17 \sqrt{P}$ for 80 - 800 MHz $D = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz  Where P is the maximum power in watts (W) and D is the recommended separation distance in meters (m).  Field strengths from fixed transmitters, as determined by an electromagnetic site survey <sup>1</sup> , should be less than the compliance level <sup>2</sup> . Interference may occur in the vicinity of equipment containing the symbol:  
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	
<p><b>NOTE:</b> With 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>These guidelines are not applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and people.</p> <p><sup>1</sup> The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcasts, and TV stations cannot be determined precisely. To determine the electromagnetic environment of a stationary transmitter, a study of the location is required. If the measured field strength at the location where the <b>STR-5000</b> is used exceeds the compliance levels given above, observe the unit very closely during use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.</p> <p><sup>2</sup> Within the frequency range of 150 kHz to 80 MHz, the field strength should be below 3 V/m.</p>			

**Table B-2: Electromagnetic Immunity Compatibility (cont'd)**

**Separation from RF Equipment**

The **STR-5000** Stroboscopy Unit is intended for use in electromagnetic environments in which disturbances are controlled. Users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the **STR-5000** Stroboscopy Unit as recommended below, according to the maximum output power of the communications equipment.

NOMINAL TRANSMITTER OUTPUT (W)	SEPARATION DISTANCE IN METERS		
	150 kHz to 80 MHz $D = 1.17 \sqrt{P}$	80 MHz to 800 MHz $D = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $D = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters whose maximum nominal output is not listed above, the recommended separation distance D can be determined using the distance equation in the columns above that correspond to the frequency of the unit. P is the maximum nominal output of the transmitter in watts.

**NOTE:** With 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines are not applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and people.

**Table B-3: Separation Between STR-5000 Unit and RF Equipment**



# Cogentix

Medical

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**Manufactured for:**

**Cogentix Medical, Inc.**  
40 Ramland Road South  
Orangeburg, NY 10962  
Tel.: 866 258-2182 (toll free in U.S.)  
Tel.: (+1) 952 426-6189 (international)  
Fax: 866 255-4522 (toll free in U.S.)  
Fax: (+1) 952 426-6199 (international)  
email: [customercare@kogentixmedical.com](mailto:customercare@kogentixmedical.com)

*[www.kogentixmedical.com](http://www.kogentixmedical.com)*

**For additional product information or questions pertaining to sales and service, please contact the local distributor or the manufacturer.**



**MedPass International, Ltd.**  
Windsor House, Bretforton  
Evesham, Worcestershire  
WR11 7JJ, United Kingdom

