SpectraScience
INNOVATIONS IN CANCER DETECTION

WavSTAT4™ Optical Biopsy System

International User's Manual

CAUTION: LOCAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR LICENSED HEALTH CARE PROVIDER WHO HAS COMPLETED TRAINING IN THE USE OF THE DEVICE

CAUTION: THE USER SHOULD READ AND UNDERSTAND THE OPERATING INSTRUCTIONS, INCLUDING INDICATIONS, WARNINGS AND PRECAUTIONS, BEFORE PERFORMING ANY PROCEDURE. FAILURE TO DO SO MAY RESULT IN INJURY TO THE PATIENT OR THE OPERATOR, OR DAMAGE TO THE SYSTEM.

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SpectraScience
INNOVATIONS IN CANCER DETECTION

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CAUTION:

Local Law restricts this device to sale by or on the order of a physician who is trained in the use of the device in gastrointestinal (GI) endoscopy.

1.0 Device Description

The WavSTAT4® Optical Biopsy System (WavSTAT4 OBS, WavSTAT4 system) consists of a laser source, Optical Biopsy Forceps (optical fiber with forceps), a spectrometer, analytical software, and user-interface unit. The system is used with standard gastrointestinal endoscopic equipment. The laser source is a 337-nanometer wavelength nitrogen pulsed laser. It provides the light energy used in the system. The light energy is transmitted through the optical fiber and is absorbed by the target tissue. In turn, the light is returned to a spectrometer through the same optical fiber, and is interpreted by the analytical software, which includes an algorithm through which the target tissue is classified as "suspect" or "not suspect." The user-interface unit then displays this classification to the user.

The unit, which operates on standard 100-240VAC / 50/60 Hz power, contains: the spectroscopy subsystem that consists of the laser, optics, and photon detection system; a RFID reader that identifies the Optical Biopsy Forceps; and a touch screen display. The high-resolution screen displays results of tissue analysis, step-by-step instructions, procedure summary, and system status. WavSTAT4 System data are stored on an internal Storage Media and can be downloaded to a USB memory device.

2.0 Indications for Use

The SpectraScience WavSTAT4 system is intended to be used as an adjunct to gastrointestinal (GI) endoscopy. See specific application instructions.

3.0 Contraindications

The use of this device is contraindicated in patients who:

- Have pre-existing abnormalities of the coagulation system which contraindicate endoscopic biopsy.
- Have other conditions that prevent endoscopic biopsy.

4.0 Warnings and Precautions

4.1 Clinical

4.1.1 See application instructions for clinical information.

4.2 Technical

4.2.1 Do not use the equipment in the presence of a flammable anesthetic mixture that contains air, oxygen or nitrous oxide.

4.2.2 Do not point the tip of the Optical Biopsy Forceps toward the eye.

4.2.3 Do not attempt access or service of internal parts. Contact with internal components may result in electrical shock and Class 3B laser emission. Contact SpectraScience or you local Distributor for service.

4.2.4 The available USB port is designed to be used with a memory device. Do not install any other device while the unit is in use.

4.2.5 Do not lean or push the unit from the side with a load of 58 N. This will cause the unit to tip over and may pose a hazard to the operator or bystanders.

4.2.6 The system is a Class 1 Laser Product and conforms to the applicable requirements of 21 CFR part 1040, and EN60825-1, second edition, 2007-03.

4.2.7 Viewing the laser output with certain optical instruments (example: eye loupes, magnifiers and microscopes) within a distance of 100 mm may pose an eye hazard.

LASER RADIATION
DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS
CLASS 1M LASER PRODUCT

4.2.8 The system incorporates a Class 3B pulsed nitrogen laser which emits light energy at a wavelength of 337.1 nm. Access to the Class 3B pulsed nitrogen laser can only be achieved if the system enclosure cover is removed. There are no user adjustable settings within the WavSTAT4 system. Only trained service personnel shall open the system enclosure, which allows access to energy levels greater than Class I.

Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

4.2.9 The WavSTAT4 system is a Class I, type BF, IPXO continuous use and not for AP/APG. (See Section 13.2 for Glossary of Abbreviations)

4.2.10 This equipment has been tested and found to comply with the limits for medical devices to IEC 601-1-2:2004/11/01 Ed: 2.1. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one of more of the following measures:

1. Reorient or relocate the device.
2. Increase the separation between the devices.
3. Connect the equipment to an outlet on a different electrical circuit.
4. Consult the manufacturer or field service technician for help.

5.0 Adverse Events

During clinical testing of the device, no adverse events were observed.

6.0 System Components

6.1 Maintaining Device Effectiveness (See Section 8)

6.2 System Components Recommended for Proper Operation

6.2.1 WavSTAT4 OBS Model 4

The unit is supplied fully assembled in units of one (1).

The unit shall be used with SpectraScience accessories only. This includes the supplied activation footswitch, power cord and Optical Biopsy Forceps.

6.2.2 Optical Biopsy Forceps

The Optical Biopsy Forceps are supplied single use 5 pack sterile. Optical Biopsy Forceps are available in a length of 230cm for use with full length endoscopes.

6.3 Optical Biopsy Forceps

Current Models of Optical Biopsy Forceps (integrated optical fiber).

Types	Suggested Endoscope Working Length	Optical Biopsy Forceps Working	Total Length of Optical Fiber	Optical Biopsy Forceps Catalog No.
Single Use, Sterile	Full Length	230 cm	5.0 meters	900016-002

Optical Biopsy Forceps contain an optical fiber. The Optical Biopsy Forceps with the integrated fiber are used to obtain spectral data and can also be used to obtain a physical biopsy.

Note: For further information on Optical Biopsy Forceps refer to the Optical Biopsy Forceps Instructions for Use (800105-002) provided with 900016-002.

6.4 Method of Operation

The WavSTAT4 system employs laser induced auto-fluorescence technique to obtain spectral information. The system transmits low level monochromatic laser light energy through an optical biopsy forceps. The tissue in contact with the optical fiber absorbs the light and emits a characteristic spectral signature. The resulting tissue auto-fluorescence is transmitted via the same optical fiber to a detector within the unit. Resulting spectral information is analyzed by the computer. An icon appears on the touch screen display with analysis results of either "suspect" (RED) or "not suspect" (GREEN) or inconclusive (Amber).

The WavSTAT4 system excitation source is a pulsed nitrogen laser. The laser emits light energy at a wavelength of 337 nanometers. The laser pulse energy entering the Optical Biopsy Forceps is set by SpectraScience, Inc., and is not user-selectable. The system software is configured to allow simultaneous tissue excitation, data collection and analysis in less than 2 seconds, each time the footswitch is depressed.

6.5 Unit

See Figure 1 to locate the following list of items.

6.5.1 Optical connector

The optical connector on the front of the unit is the site at which optical biopsy forceps are connected to the unit

6.5.2 Power Switch

The Power Switch controls power to system.

6.5.3 Audible Signal (Not Pictured)

The audible signal alerts the user aurally that a verified sequence has been obtained.

6.5.4 Touch Screen Display

The touch screen displays system status, procedure steps, tissue analysis results and user selectable functions.

See Figure 2 to locate the following items.

6.5.5 Communication Ports

This section contains ports for USB, RJ45, PS2 and VGA Connections.

6.5.6 System Labels

The system labels contain the system part number, serial number, manufacturer's name and safety information.

6.5.7 Power Cord Connection

The power cord connection is indexed so the power cord connects in only one way.

6.5.8 Ventilation Fans

The ventilation fans provide cooling for the unit during use.

6.5.9 Footswitch

The footswitch, connected to the back of the unit with a four-pin connector, activates the spectroscopic subsystem to obtain a verified sequence.

Figure 1. Front View of Unit

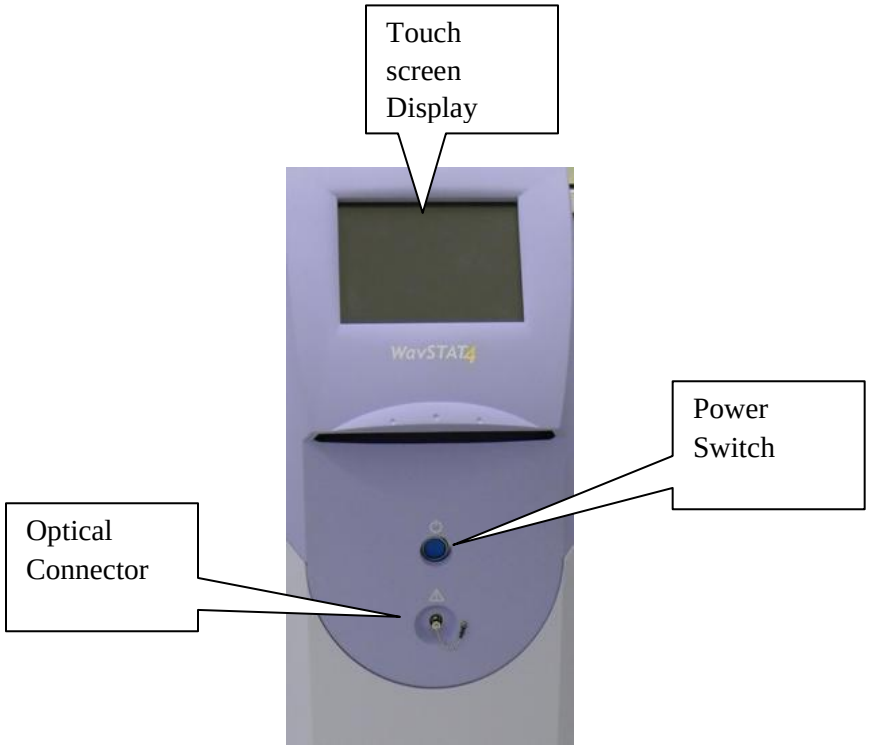
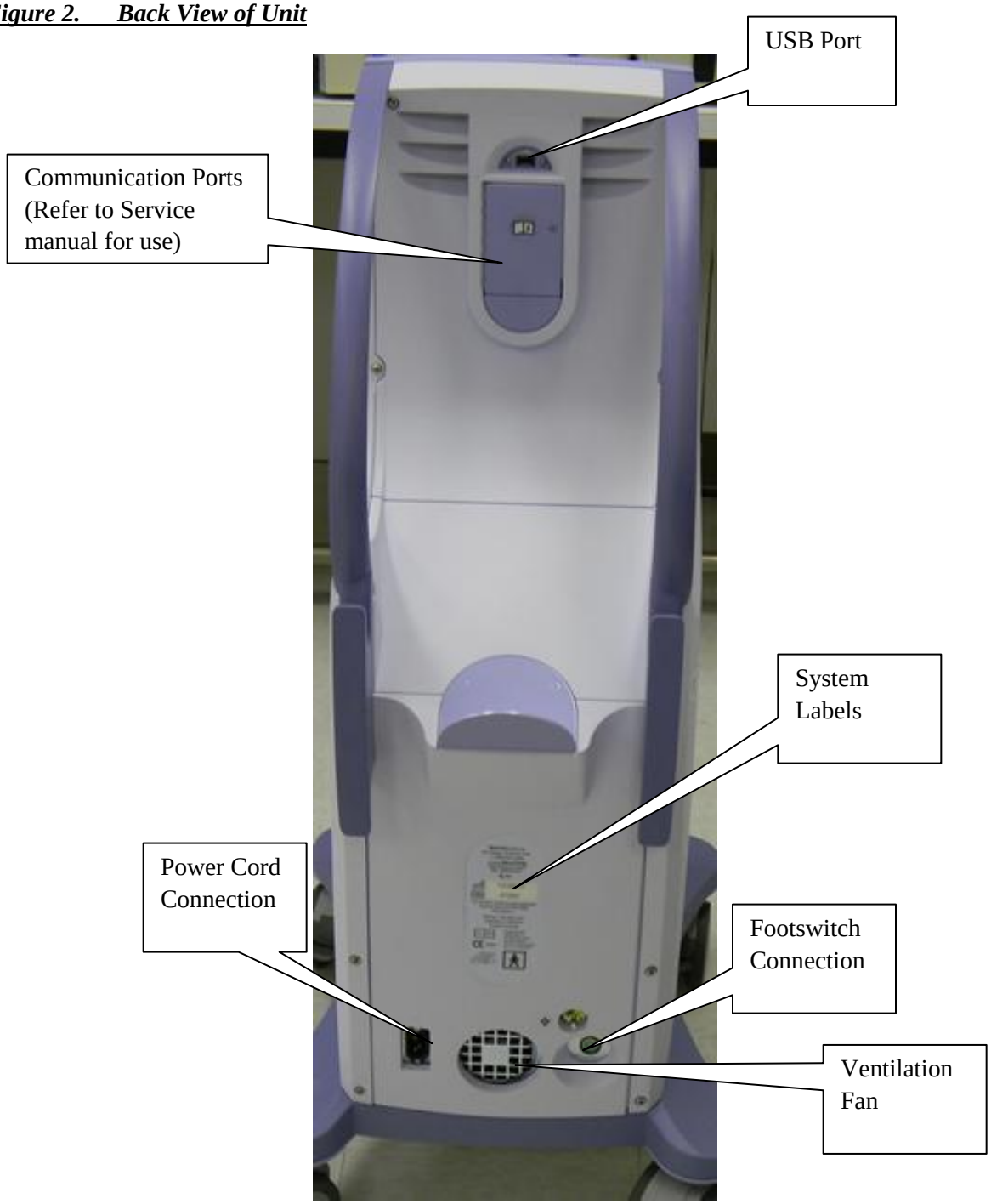


Figure 2. Back View of Unit



6.6 Touch Screen Display

See Figure 3 and 3a to locate the following list of items.

6.6.1 User Selectable Functions

The touch keys across the top of the touch screen display identify functions.

- A key is "active" when the name of the function appears in black letters. When an active key is pressed the identified function is activated
- A key is "inactive" when the name of the function appears in gray letters.

The user can select the following system functions:

6.6.1.1 Begin Procedure - starts a procedure for each patient.

6.6.1.2 Export to USB- allows the user to export procedure information from the last procedure onto the USB flash drive.

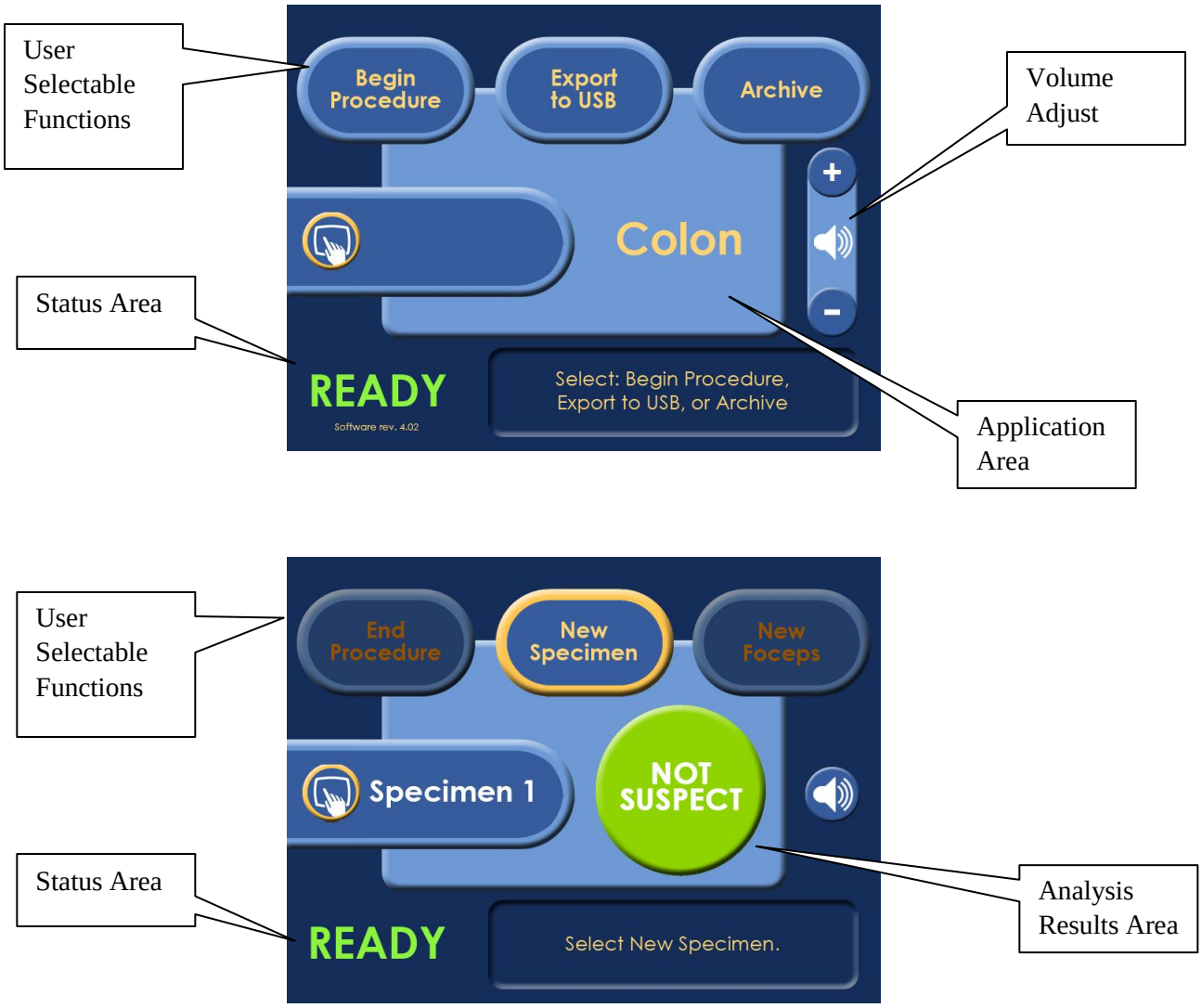
6.6.1.3 Archive - allows the user to archive the spectral data onto a USB flash drive.

6.6.1.4 New Specimen - prepares the system for the next tissue specimen.

6.6.1.5 New Forceps - instructs the user to replace the Optical Biopsy Forceps if it is damaged or fails calibration.

6.6.1.6 End Procedure – allows the user to end the current procedure.

Figure 3. & 3a. Touch Screen Display Layout Example



6.6.2 Specimen Number

6.6.2.1 The specimen number is displayed in the left side of the screen.

6.6.2.2 Prior to collecting specimens, a background sample is collected. While this is in progress, "Background" is displayed in place of the specimen number.

6.6.3 Analysis Results Area

The right side of the screen displays the analysis results icon.

Analysis Result	Icon Color / Shape	Message
Non-Neoplastic or Hyperplastic	Green / Circle	
Neoplastic or Cancerous	Red / Octagon	
Inconclusive	Amber/Triangle	

6.6.4 Status Area

The bottom of the screen displays real time status of the system/procedure and guides the user to the next step in the procedure. In the event of a problem, this area displays a possible solution.

6.6.5 Patient Information Entry Box (Not Pictured)

When "END PROCEDURE" is pressed a message box appears that asks the user to enter patient information. Either an alpha or numeric keyboard can be selected to enter relevant patient data.

7.0 Instructions for Use

Note: For further information on WavSTAT4 use refer to Quick Reference Guide (800319-002).

8.0 System Maintenance

8.1 Maintenance Performed by Manufacturer or Distributor

An inspection and any necessary preventive maintenance will be performed every six (6) months by a *Spectra*Science trained service technician. Contact SpectraScience, Inc. or the local Distributor for Technical Support.

Note: The WavSTAT4 unit has No User Serviceable Parts inside.

8.2 Maintenance Performed by Hospital Staff

8.2.1 Unit – use a damp cloth with mild soap solution and carefully wipe the unit top and sides as necessary. **Never use cleaning solutions**.

8.2.2 Touch screen display- use a damp cloth with mild soap solution and carefully wipe the touch screen display using light pressure. **Never use cleaning solutions**.

9.0 Command Summary

The following chart lists the user selectable functions displayed on the touch screen display and its use.

Command	Use
BEGIN PROCEDURE	Initiates the start of a procedure, including optical biopsy forceps setup
NEW SPECIMEN	Indicates that a new specimen will be sampled.
NEW FORCEPS	Initiates change to a new forceps
END PROCEDURE	Ends the data acquisition procedure for a given patient.
EXPORT TO USB	Allows the user to export information to a USB Flash Drive.
ARCHIVE	Initiates archiving of spectral data onto a USB flash drive

10.0 Error Messages and Resolution

The system will alert the user to problems. Error messages appear in the "Status Area" on the touch screen display (Fig 3, section 6.6) or a message box may appear in the center of the touch screen display.

10.1 Power Up Error Definitions

Error #	Description	Resolution
001	Detector Error	Contact Technical Support *Please reference error message number or error message text*
002	Digital I/O Error	
003	Disk Free Space Error	
004	INI File Error	
005	INI Setting Error	
006	INI Range Error	
007	Calibration File Error	
008	Calibration Setting Error	
009	Binary File Error	
010	Language DLL Error	
011	RFID Tag Code Reader Error	
012	Institution Name Error	
013	Smooth File Error	
014	Startup Range Error	
015	Wavelength Range Error	

10.2 Startup Error Definitions

10.2.1 Errors in this range must first be resolved by the following: "**Leave Protective Cap on Forceps".** If this does not resolve and/or the message "MSG_CONTACT_TECH", please contact Technical support.

Error #	Description	Resolution
100	Frame Number Error	Contact Technical Support *Please reference error message number or error message text*
110	Frame Orientation Error	
130	Sample Intensity Minimum Error	
140	Sample Intensity Variation Error	
150	Signal Laser Off Intensity Range	
160	Aberrant Diode Error	
170	Detector Saturation Error	
180	Background File Error	
190	Detector Cooler Error	

10.3 Background Error Definitions

10.3.1 Errors in this range must first be resolved by the following: "**Leave Cap on Optical Biopsy Forceps and depress footswitch"** If this does not resolve and/or the message "MSG_CONTACT_TECH", please contact Technical support.

Error #	Description	Resolution
200	Frame Number Error	Contact Technical Support *Please reference error message number or error message text*
210	Frame Orientation Error	
220	Sample Intensity Minimum Error	
230	Sample Intensity Variation Error	

10.4 Additional Error messages

10.4.1 Errors in this range may be resolved by following the recommended actions listed in the table below.

Message	Resolution
Footswitch not connected	Connect footswitch to rear of unit
Signal Error, Reposition Optical Biopsy Forceps	Fiber not in contact with specimen or movement occurred during acquisition. Reposition Optical Biopsy Forceps. Depress footswitch.
Replace Optical Biopsy Forceps	Disconnect Optical Biopsy Forceps. Replace with new Optical Biopsy Forceps.
No media in drive	Insert USB Flash Drive.

11.0 Technical Support

All questions / comments / concerns will be answered by trained personnel at:

*Spectra*Science, Inc.
11568 Sorrento Valley Rd, Suite 11
San Diego, CA 92121
Telephone: +1.858.847.0200
Facsimile: +1.858.847.0880
info@spectrascience.com

- or- contact your local Distributor.

12.0 System Information

12.1 System Specifications

Item	Specification
Classification	
• Type of protection against Electrical Shock	Class I
• Degree of protection against electrical shock	Type BF Applied Part
• Degree of protection against ingress of water	System: IPX0 Footswitch: IP68
CPU	Pentium M, single board
Operating System	Windows Embedded Standard 2009
Electrical	
Voltage	100 - 240 VAC / 50/60Hz
Current	0.7A
Laser	337.1 nm Nitrogen Pulsed
Repetition Rate	8 Hz
Transport and Storage Conditions	
Temperature Range	-20ºC to +50ºC (-4ºF to 122ºF)
Relative Humidity Range	20% to 80%
Atmospheric Pressure Range	70.0 kPa to 106.0 kPa
Operating Conditions	
Temperature Range	10ºC to +40ºC (50ºF to 104ºF)
Relative Humidity Range	20% to 80%
Weight	102.5 lb. (46.5 kg.) approximately

Outside Dimensions	Height: 43.75” (111.1 cm) approximately Width: 24.5” (62.2 cm) approximately Depth: 24.5” (62.2 cm) approximately
Biocompatibility	Biocompatibility for the system does not apply.
Cleaning	Unit – use a damp cloth with mild soap solution and carefully wipe the unit top and sides as necessary. **Never use cleaning solutions.** Touch screen display- use a damp cloth with mild soap solution and carefully wipe the touch screen display using light pressure. **Never use cleaning solutions.**

CAUTION: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

12.2 System Life Expectancy

SpectraScience guarantees supply of spare parts for the WavSTAT 4 Console for at least 8 years after date of purchase. The life expectancy and availability of some components of the WavSTAT4 console is dependent on End Of Life (EOL) notices we receive from our suppliers. We will make every attempt to find alternative sources of supply after the initial 8 year period, but cannot guarantee such an alternative supplier can be found.
At the end of life, the system shall be disposed of by your institution. The risk of the user disposing of the system is negligible if Local/State/Federal regulations are followed for electronic disposal.

Optical Biopsy Forceps shall be disposed of using standard methods as defined by the institution of use. The risk of the user disposing of the forceps is negligible if biohazard standards are followed

12.3 Return Policy

For detailed information on SpectraScience, Inc. Returned Materials Policy, please contact our Customer Service Department, or your local Distributor.

SpectraScience, Inc. Customer Service Department:

Telephone: +1.858.847.0200 or Facsimile: +1.858.847.0880 or info@spectrascience.com

13.0 Glossary of System Symbols

13.1 Chart of System Symbols

Symbol	Meaning
	Alternating current
	Off (power disconnection from mains)/ On (power connection to mains)
	Type “BF” equipment
	Attention, consult accompanying documents
	Protective earth (ground)
	Consult Instruction Manual For Use

13.2 Glossary of Definitions / Abbreviations

13.2.1 Class I:

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

13.2.2 Type BF (Type B equipment with an F-Type applied part)

Equipment that provides a particular degree of protection against electrical shock, particularly regarding allowable leakage current, and reliability of protective earth protection.

13.2.3 Type F applied part:

A part that is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth (applied part is the part of equipment that comes in direct contact with the patient).

13.2.4 IPXO (Ingress protection rating):

No protection against moisture.

13.2.5 AP/APG:

AP: Equipment complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a flammable anesthetic mixture with air.

APG: Equipment complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a flammable anesthetic mixture with oxygen or nitrous oxide.

13.2.6 Continuous Use Operation:

Operation of the WavSTAT4 system under normal load for an unlimited period, without the specified limits of temperature being exceeded.

14.0 Definition of System Icons

The following icons appear during system operation when the user is asked to make a decision to proceed.

Icon	Meaning
Yes	The user confirms to proceed with the displayed selection.
No	The user confirms not to proceed with the displayed selection.
OK	The user acknowledges that the message has been understood and elects to proceed.
Cancel	The user elects to discontinue the displayed selection.

15.0 Patient's Manual

NOT APPLICABLE

16.0 Disclaimer of Warranties

SpectraScience, Inc. makes no warranty, expressed or implied, by operation of law or otherwise, beyond the warranty that reasonable care was used in the manufacture of the products and that material and labor employed in the manufacture will be free from defects for a period of one year from the date of first shipment.

This warranty is inclusive and in lieu of all other warranties whether written, oral, expressed or implied (including, but not limited to, any warranty of merchantability of fitness for a purpose). SpectraScience, Inc shall not be held liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of these products, other than replacement or refund of the purchase price. SpectraScience neither assumes nor authorizes any other person to assume on its behalf any other additional liability or responsibility in connection with this device. No representative of the company may change any of the foregoing and the buyer hereby accepts the products subject to the terms herein.

This disclaimer of warranty is dictated by the many elements which are beyond the control of SpectraScience, Inc., such as diagnosis of patient, conditions under which the system is used, methods of administration or handling of the system after it leaves the possession of SpectraScience, Inc., sterilization procedures, execution of recommended procedures, and others.

17.0 Trademarks

*Spectra*Science® WavSTAT4 ®, WavSTAT4 ® Optical Biopsy System, WavSTAT4 ® Optical Biopsy Forceps and WavSTAT4 ® Optical Biopsy Fiber are Registered Trademarks of *Spectra*Science, Inc.

18.0 Conformance to Standards

The WavSTAT4 Optical Biopsy System and Optical Biopsy Forceps conform to all applicable standards revisions by FDA and the European Union. For a complete list of standards, please contact *Spectra*Science, Inc.

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