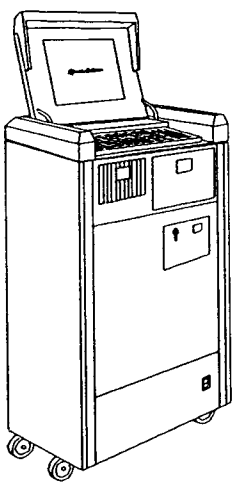
Optical Biopsy™ System

System User's Manual

Model Number: OBS/L



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FIGURES

CAUTION - **Federal Law restricts this device to sale by or on the order of a physician who is trained in the use of the device and in lower gastrointestinal endoscopy.**

1.0 BRIEF DEVICE DESCRIPTION

The Optical Biopsy System (OBS) system consists of a laser source, an optical fiber, analytical software, and user-interface console. The system is used with standard lower-gastrointestinal endoscopic equipment and biopsy forceps. The laser source is a 337 nanometer wavelength nitrogen pulse 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 polyp. In turn, the light is returned through the 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 console then displays this classification to the user.

2.0 INDICATIONS FOR USE

The SpectraScience™ Optical Biopsy™ System (OBS) is intended to be used as an adjunct to lower gastrointestinal (GI) endoscopy. The device is intended for the evaluation of polyps less than 1 cm in diameter that the physician has not already elected to remove. The device is only to be used in deciding whether such polyps should be removed (which includes submission for histological examination).

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 and/or polypectomy.
- Have other conditions that prevent endoscopic biopsy or removal of colonic polyps.
- Have familial polyposis.

4.0 WARNINGS AND PRECAUTIONS

Clinical

WARNING: **If this device is used when the physician, absent this device, would remove all visualized polyps, this device will lead to an increase in the number of potentially pre-cancerous or cancerous polyps that are not removed (i.e., it will decrease the physician's sensitivity).**

- The device is only to be used by **physicians** trained in lower GI endoscopy.
- The safety and effectiveness of this device has not been evaluated in determining the need for colonoscopic follow-up of polyps visualized but not biopsied during sigmoidoscopy.
- If this device is used when a physician, absent this device, would only remove polyps that his/her visual assessment suggests are adenomatous, then this device will not only increase the number of removed polyps that turn out to be pre-cancerous or cancerous, but will also increase the number of removed polyps that turn out to be hyperplastic (i.e., while the device will increase the physician's sensitivity, it will also decrease her/his specificity).

- The safety and effectiveness of this device to guide the performance of subtotal biopsy of polyps has not been established.

- To properly use the device, the physician must move the fiber to three different regions of the same polyp and obtain three distinct spectral measurements. The accuracy of the device to distinguish between "suspect" and "not-suspect" polyps is dependent upon obtaining three distinct measurements from each polyp.

- To properly use the device, the physician must obtain a spectral reading from normal tissue within the patient's colon. The device cannot provide an evaluation without this information.

- The OBS is not intended to be used as a stand-alone device. It must be used in combination with the physician's judgement in the evaluation of colonic polyps.

Technical

- Do not use the equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

- Do not point the tip of the optical fiber toward the eye.

- The optical fiber is provided sterile and intended for single use only. Do not re-sterilize or reuse.

- Do not attempt access or service of internal parts. Contact with internal components may result in electrical shock. Contact SpectraScience for service.

- Do not attempt to remove the keyboard or display from the console.

- Do not insert a used or non-sterile fiber into the background fixture of the unit.

- The equipment has been tested for use in industrial/hospital environments. The use of the device in other environments may cause electromagnetic or other interference with nearby devices.

- The device contains a Class I UV laser source and conforms to the applicable requirements of 21 CFR part 1040.

5.0 ADVERSE EVENTS

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

Potential adverse events that may be observed during the use of this device include:
- inadvertent perforation of the colon with the optical fiber or components;
- excessive exposure of laser energy to patient due to device malfunction;
- standard risks associated with sigmoidoscopy and colonoscopy; and
- excessive bleeding.

6.0 CLINICAL STUDIES

The clinical studies of the OBS system were conducted in two phases.

Phase I

In the first phase (Phase I), data were collected to develop the diagnostic algorithm to be validated in the Phase II study. A total of 183 specimens from 86 patients at three investigational sites were evaluated in the Phase I study. Background information on these study participants is given in Table 1. Complete spectral characterization, the endoscopist's visual assessment, and consensus pathology diagnoses were obtained for 97 polyps and 86 "normal" control tissue samples.

TABLE 1 - BACKGROUND INFORMATION FROM PHASE I STUDY

Characteristic	Male	Female	Total
Number of subjects	56	30	86
Age, range (years) mean ± standard deviation (SD)	45-86 63.39 ± 9.52	40-86 64.86 ± 15.93	40-86 63.89 ± 12.06
Number of polyps evaluated	64	33	97
true adenomas biopsied	35	21	56
true hyperplastic polyps biopsied	19	8	27
polyps classified as "normal"	10	4	14

The "true" status of each polyp, as classified above, was determined by histological examination. Polyps were classified as adenomatous, hyperplastic, or "normal" and ranged in size from 3 - 25 mm. The "normal" classification refers to those tissue samples which during endoscopic evaluation were thought to be polyps, but were determined to be normal tissue during the histological exam.

Based on the data obtained from this study, an algorithm was developed that evaluated the spectral characteristics to distinguish between adenomatous and hyperplastic polyps.

Phase II

The purpose of the Phase II study was to validate the algorithm developed from the Phase I study, i.e., to measure the ability of the OBS device during colonoscopy to discriminate between adenomatous and hyperplastic polyps by classifying them as "suspect" or "not suspect," respectively.

Study Design:

The Phase II trial was a prospective, non-randomized, multi-center study of 101 subjects at 5 sites. Patients who participated in the study had been previously referred to colonoscopy and had at least one polyp identified. The patient's participation in the study was limited to the single colonoscopy procedure where the device was used (i.e., the patient was not followed after the completion of the procedure). The results of the OBS analysis were not known to the physician; therefore, patient treatment was not affected.

Patients Studied:

The baseline characteristics of the patients studied are presented in Table 2.

TABLE 2 - BACKGROUND INFORMATION FROM PHASE II STUDY

Characteristic	Male	Female	Total
Number of subjects	61	40	101
Age, range (years) mean ± SD	30-91 60.99 ± 6.53	50-83 67.22 ± 4.36	30-91 63.57 ± 6.12
Number of polyps identified	107	70	177
Number of polyps evaluable†	79	56	135
true adenomas biopsied	45	36	81
true hyperplastic polyps biopsied	20	15	35
polyps classified as "normal"	14	5	19

† The number of polyps evaluable is defined as those polyps for which a complete spectral analysis was performed and for which a normal tissue biopsy was obtained. The number of subjects is based on the number of polyps evaluable, and not the total number of polyps identified.

The inclusion criteria for the study included:

- presence of at least 1 polyp on prior endoscopic examination.

The exclusion criteria included:

- coagulopathy or other conditions contraindicating endoscopic biopsy or polypectomy;
- other conditions which prevent the removal or biopsy of colonic polyp;
- presence of familial polyposis.

Methods:

Patients were prepared for a standard colonoscopy procedure according to the practice at each investigational site. The optical fiber and forceps were inserted through the working channel of the colonoscopy.

When a polyp was identified, the physician documented: (1) whether they believed the polyp was adenomatous (or pre-cancerous, pre-malignant) or hyperplastic based on their visual assessment; and (2) whether they would remove the polyp. The OBS probe was then applied to the polyp.

The "test" spectral measurements were obtained in the following manner: The optical fiber was placed on a region of the polyp; the OBS pedal was depressed, triggering the release of laser energy to the polyp; the tissue's autofluorescence was reflected back through the fiber and evaluated by the analytical software. This step was repeated, such that spectral information from three different locations on the polyp were obtained. If the OBS was unable to decipher all three measurements, then the diagnostic procedure was not completed and the polyp was considered unevaluable. A "normal" control spectral measurement was obtained on a region of "normal" mucosa near the location of the target polyp. Once three spectral polyp readings and a "normal" reading were obtained, the data were processed through the system algorithm. During the study, the physician performing the procedure was blinded to the system results. The polyp was then biopsied.

All tissue samples were evaluated by two pathologists to confirm histology. This included a "reference" pathologist who evaluated all specimens, as well as the institutional pathologist who regularly evaluated specimens at that site. If the diagnoses by the pathologists differed, then the tissue sample was reevaluated by each pathologist. If the diagnoses differed a second time, then the specimen was excluded from further analysis.

Effectiveness Results:
The effectiveness of the OBS is characterized by its ability to correctly identify adenomatous polyps as adenomatous (characterized as the sensitivity of the machine) and to correctly identify hyperplastic polyps as hyperplastic (characterized as the specificity of the machine). The data presented below include those polyps 1 cm or smaller in size that were evaluable in the Phase II study. Polyps were considered "evaluable" if a complete spectral data set was obtained on both the target polyp and the adjacent "normal" tissue, and if all documentation was complete.

Sensitivity/Specificity Results
The sensitivity and specificity of the device alone, physician alone (based on visual assessment), and combined device and physician are presented in Tables 3, 4, and 5, respectively.

TABLE 3 - SENSITIVITY/SPECIFICITY OF OBS ALONE
n = 135 evaluable polyps ≤ 1 cm

		Pathology	
		Adenomatous	Hyperplastic
Device Alone	Adenomatous	64	24
	Hyperplastic	17	30
	Sensitivity	79.0% (68.5-87.3)	
	Specificity	55.6% (41.4-69.1)	
	False Positive Rate	44.4%	
	False Negative Rate	21.0%	

TABLE 4 - SENSITIVITY/SPECIFICITY OF ENDOSCOPIST'S VISUAL ASSESSMENT ALONE
n = 135 evaluable polyps ≤ 1 cm

		Pathology	
		Adenomatous	Hyperplastic
Physician Alone	Adenomatous	67	27
	Hyperplastic	14	27
	Sensitivity	82.7% (72.7-90.2)	
	Specificity	50.0% (36.1-63.9)	
	False Positive Rate	50.0%	
	False Negative Rate	17.3%	

TABLE 5 - SENSITIVITY/SPECIFICITY OF COMBINED OBS AND ENDOSCOPIST'S VISUAL ASSESSMENT†
n = 135 evaluable polyps ≤ 1 cm

		Pathology	
		Adenomatous	Hyperplastic
Combined Device and Physician	Adenomatous	78	36
	Hyperplastic	3	18
	Sensitivity	96.3% (89.6-99.2)	
	Specificity	33.3% (21.1-47.5)	
	False Positive Rate	66.7%	
	False Negative Rate	3.7%	

† For Table 5, if either the device classified the polyp as "suspect" or the physician classified the polyp as adenomatous, then the combined classification for that polyp was adenomatous. Thus, the only case where the polyp was classified as hyperplastic was when the device classified the polyp as "not suspect" and the physician classified the polyp as hyperplastic.

The results presented above demonstrated a statistically significant improvement in sensitivity when the OBS was used in conjunction with the physician's visual assessment during colonoscopy, according to the approved Indications for Use.

Safety Results:

No adverse events (i.e., patient complications) were observed by study investigators or reported by study subjects.

7.0 HOW SUPPLIED (System Components Recommended for Proper Operation)

The OBS System is supplied fully assembled in units of one. The OBS fiber is supplied sterile, intended for single use, in quantities of one per package. The OBS forceps is supplied non-sterile.

8.0 INSTRUCTIONS FOR OPERATION

8.1 Maintaining Device Effectiveness

8.1.1 System maintenance will be performed on a regular basis by *Spectra*Science®.

8.1.2 Maintenance performed by hospital staff

8.1.2.1 Console – use a damp cloth with mild soap and carefully wipe the top and sides as necessary. Never use cleaning solutions.

8.1.2.2 Keyboard – dust with soft brush or clean with damp cloth. Do not use sprays or cleaning solutions.

8.1.2.3 Display - use a damp cloth with mild soap and light pressure. Never use cleaning solutions.

8.2 Complete Device Description

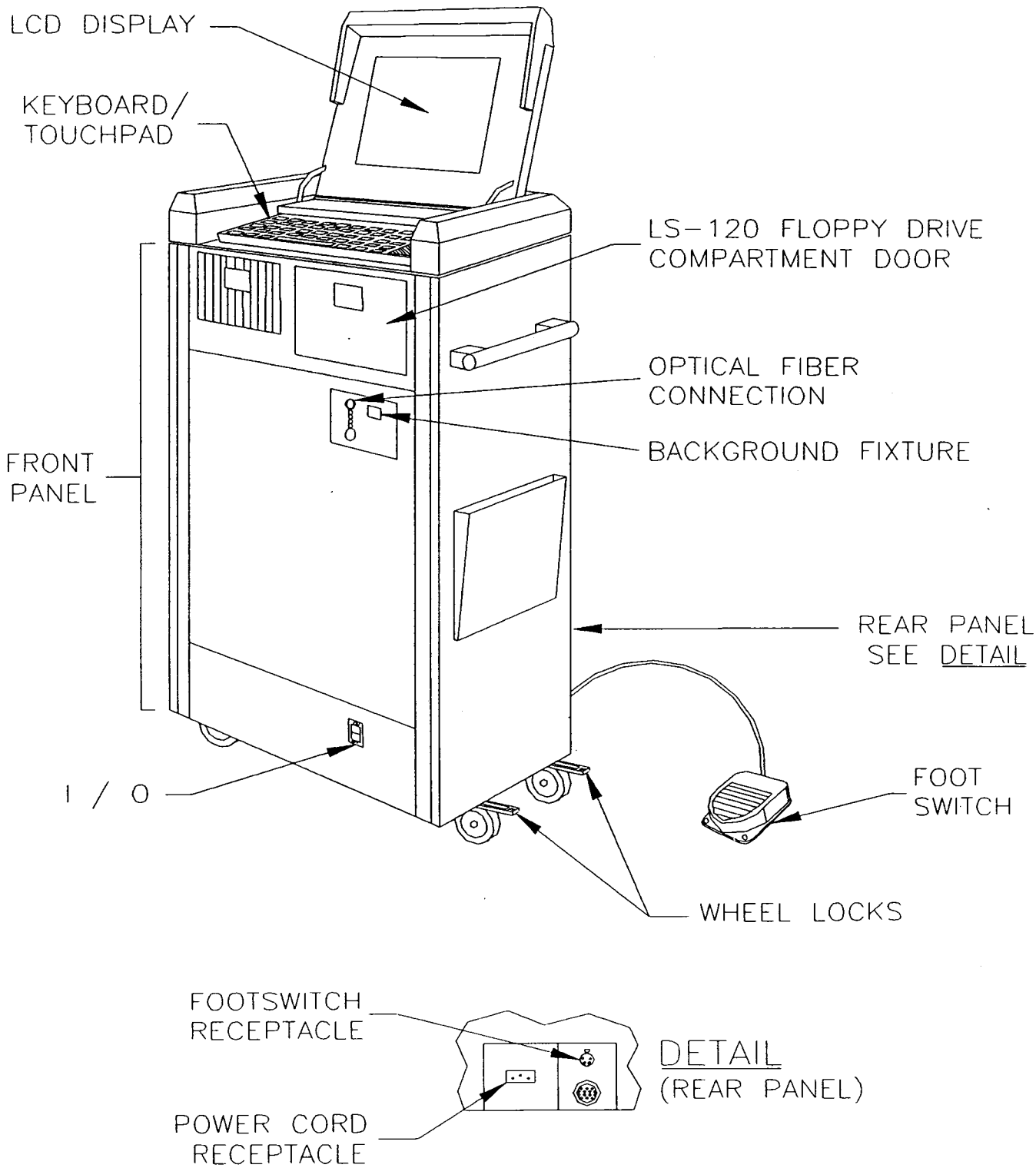
Figure 1, below, shows the location of major Optical Biopsy™ System components.

The Optical Biopsy™ Fiber is an optical fiber concentrically placed within any endoscopic accessory device (e.g., *Spectra*Science®, Inc. Optical Biopsy™ Forceps) that will accommodate and physically support in its lumen an optical fiber with an O.D. of less than 0.38mm, and can be used through a standard endoscope with a 2.8 mm I.D. working channel.

The OBS/L system employs laser induced auto-fluorescence techniques to obtain spectral information. The system transmits low level monochromatic light energy from the acquisition unit through the disposable optical fiber. The light is absorbed by the tissue in contact with the optical fiber, and the resulting tissue auto-fluorescence is collected by the optical fiber and returned to a detector within the console for measurement. Resulting spectral information is transmitted to the computer which analyzes the spectral data and displays the spectral curve and screening result.

The Optical Biopsy™ System excitation source is a pulsed nitrogen laser. The laser emits light energy in nominal 4 nanosecond pulses at a wavelength of 337 nanometers. The laser pulse energy entering the Optical Biopsy Fiber at the console is set by *Spectra*Science, Inc., and is not user-selectable. The Optical Biopsy™ System software is configured to allow simultaneous tissue excitation and data collection - in less than 2 seconds - each time the footswitch is depressed.

Figure 1 – System Components



8.2.1 Front panel

8.2.1.1 optical fiber connection and cap

8.2.1.2 background fixture

8.2.1.3 on/off switch

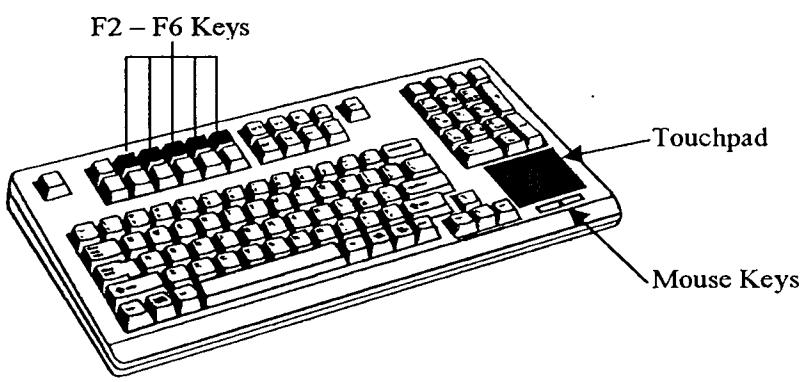
8.2.1.4 LS-120 disk drive (behind the door at top right).
Notes: 1) the LS-120 uses a regular 3.5" 1.44 Mb floppy or a high capacity 120 Mb floppy designed for the LS-120; they may be inserted only one way. 2) To access the drive press down on the black finger insertion box on the compartment door.

8.2.2 Locking wheels - two wheels of the Optical Biopsy™ System are lockable. To lock the wheels depress the outer portion of the locking tabs; release the locks by depressing the middle portion of the tabs.

8.2.3 Footswitch –activates spectroscopic subsystem; connects at lower-rear of Console with a four-pin connector. Note that the connector is indexed to fit into the receptacle only one way, and the release at the top of the receptacle must be pressed to remove the footswitch from the Console.

8.2.4 Keyboard - the OBS/L uses a keyboard with integrated touchpad for point and tap convenience.

Figure 2 – Keyboard



CAUTION
DO NOT ATTEMPT TO REMOVE THE KEYBOARD FROM THE CONSOLE.

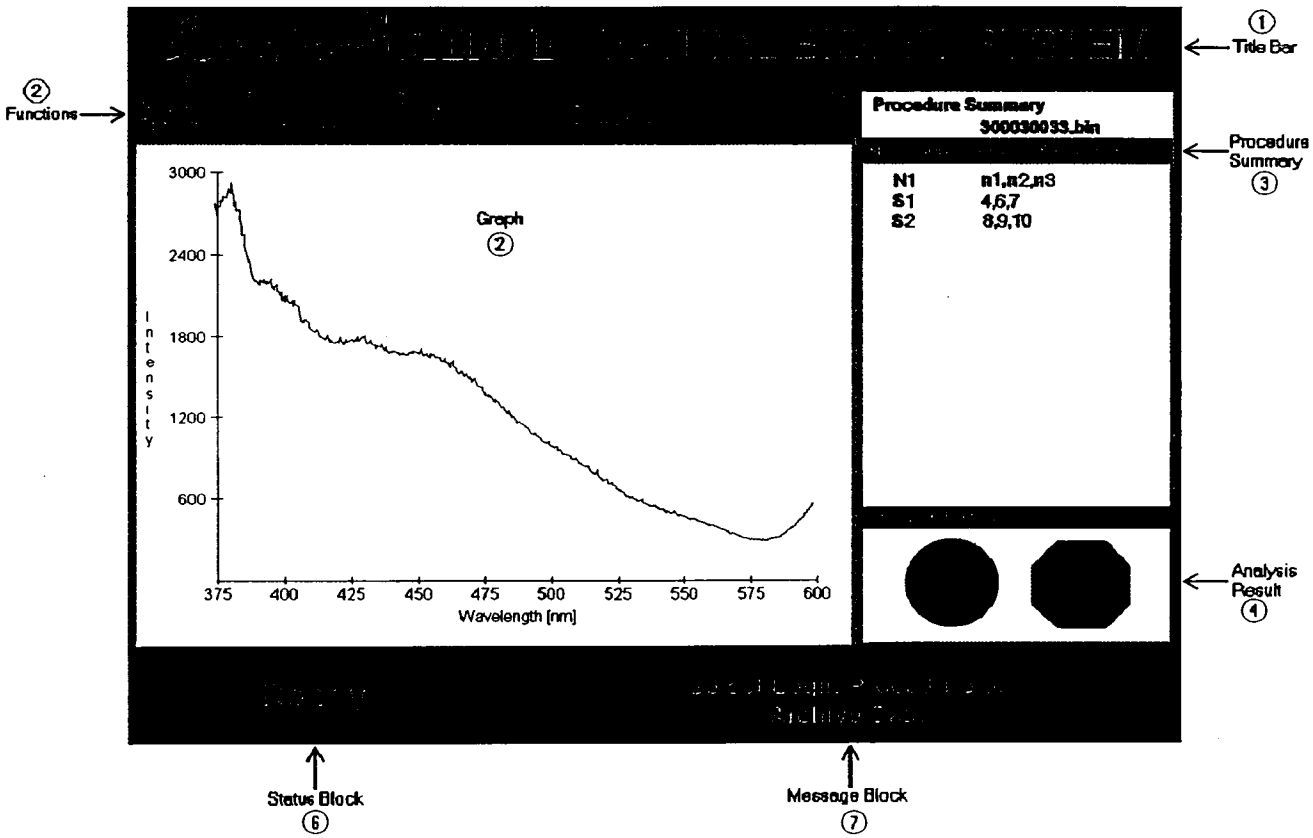
8.2.4.1 Touchpad - activated by the touch of a finger and functions like a mouse (e.g. motion across it moves the cursor in the same direction as the motion). To make a selection tap lightly on the pad.

8.2.4.2 Mouse buttons - Located directly in front of the pad are two buttons that function like left and right mouse buttons – they are an alternate means of making selections with the touchpad.

8.2.4.3 Function keys - F2 through F6 near the top-left of the keyboard are an alternate method of selecting a system function. **Note**: the F1 and F7 – F12 keys are inactive.

8.2.5 Display - An LCD display is mounted under the top cover of the console. Figure 3, below, depicts the screen layout.

Figure 3 – Display Layout



Screen area explanation (circled numbers correspond to numbered areas in Figure 3).

① Title Bar: system name and manufacturer (constant).

② Functions: blocks for selecting system functions with cursor and touchpad; F-key numbers in upper right corner of each block indicate F-key on keyboard which performs same function; only those functions that may be selected at a given time are highlighted.

③ Procedure Summary:

a) file name - (e.g.: 300030033.bin) identifies the system file that corresponds to the current procedure, and should be correlated to the patient ID for future reference; the file name changes with each procedure.

b) each normal tissue acquisition (designated for example *"N1, N2... "*), and related verified sequence count are tracked and displayed in the procedure summary block

Specimen	Verified Sequence
N1	n1,n2,n3

c) each specimen tissue acquisition (designated *"S1, S2...*) and related verified sequence count are tracked and displayed in the procedure summary block. If, for example, the second of three samples of specimen S1 was unsuccessful, the display would read:

Specimen	Verified Sequence
N1	n1,n2,n3
S1	4,6,7
S2	8,9,10

(note that verified sequence number "5", corresponding to the second sample, is not displayed):

④ Analysis Result: the following system is used to indicate whether or not the current sample site contains suspect tissue:

Analysis Result:	Icon Color / Shape:	Message:
Normal or Hyperplastic	Green / Circle	Not Suspect
Adenomatous or Cancerous	Red / Octagon	Suspect

⑤ Graph: Information displayed is for service personnel only.

⑥ Status Block: Real time status of system/procedure; this is an important reference point during procedures.

⑦ Message Block: indicates next step, or in the event of a problem, possible solution; this is an important reference point during procedures.

8.2.6 Optical Biopsy Fiber- Fiber optic core that may be integrated with accessory forceps for ease in acquiring spectral data and excising tissue for later study. See Figure 4, below.

NOTES: 1) REFERENCE INSTRUCTIONS FOR USE OF FORCEPS AND OPTICAL BIOPSY FIBER (ENCLOSED IN BOX).

2) EXTEND THE FINGER GRIPS TO OPEN THE FORCEPS; CLOSE THE FINGER GRIPS TO CLOSE THE FORCEPS.

8.3 Directions for use

8.3.1 Preparations for use

8.3.1.1 Ensure that the footswitch is securely connected to the Console.

8.3.1.2 Ensure that the connector cover is on the optical connector on the Console front panel (the cover serves as a reference during system initialization).

8.3.1.3 Press the power switch to the ON position. The automatic initialization takes approximately three to four minutes. During initialization the status block will flash **STARTUP** and the message block will show **SYSTEM INITIALIZING.**

8.3.1.4 When **READY** is displayed in the status block select **BEGIN PROCEDURE** with the F2 key or the touchpad. The optical fiber can be connected as instructed in the message block.

NOTE: THE FILE NAME (SEE PROCEDURE SUMMARY BLOCK) IDENTIFIES THE SYSTEM FILE THAT CORRESPONDS TO THE CURRENT PROCEDURE AND MAY BE CORRELATED TO THE PATIENT ID FOR FUTURE REFERENCE. THE FILE NAME CHANGES WITH EACH PROCEDURE

8.3.2 Optical Biopsy Fiber Setup

NOTE: SEE INSTRUCTIONS FOR USE FOR OPTICAL BIOPSY FIBER, OPTICAL BIOPSY FORCEPS, AND / OR OTHER ACCESSORY DEVICE.

8.3.2.1 Remove the **PROTECTIVE COVERS** from the **OPTICAL CONNECTORS** - one at the proximal end of the optical fiber and the other on the front panel optical connector.

8.3.2.2 Attach the optical fiber connector to the system optical connector.

NOTE: If using the *Spectra*Science accessory forceps follow section 8.3.3; if any other device is used, proceed to section 8.3.4, below.

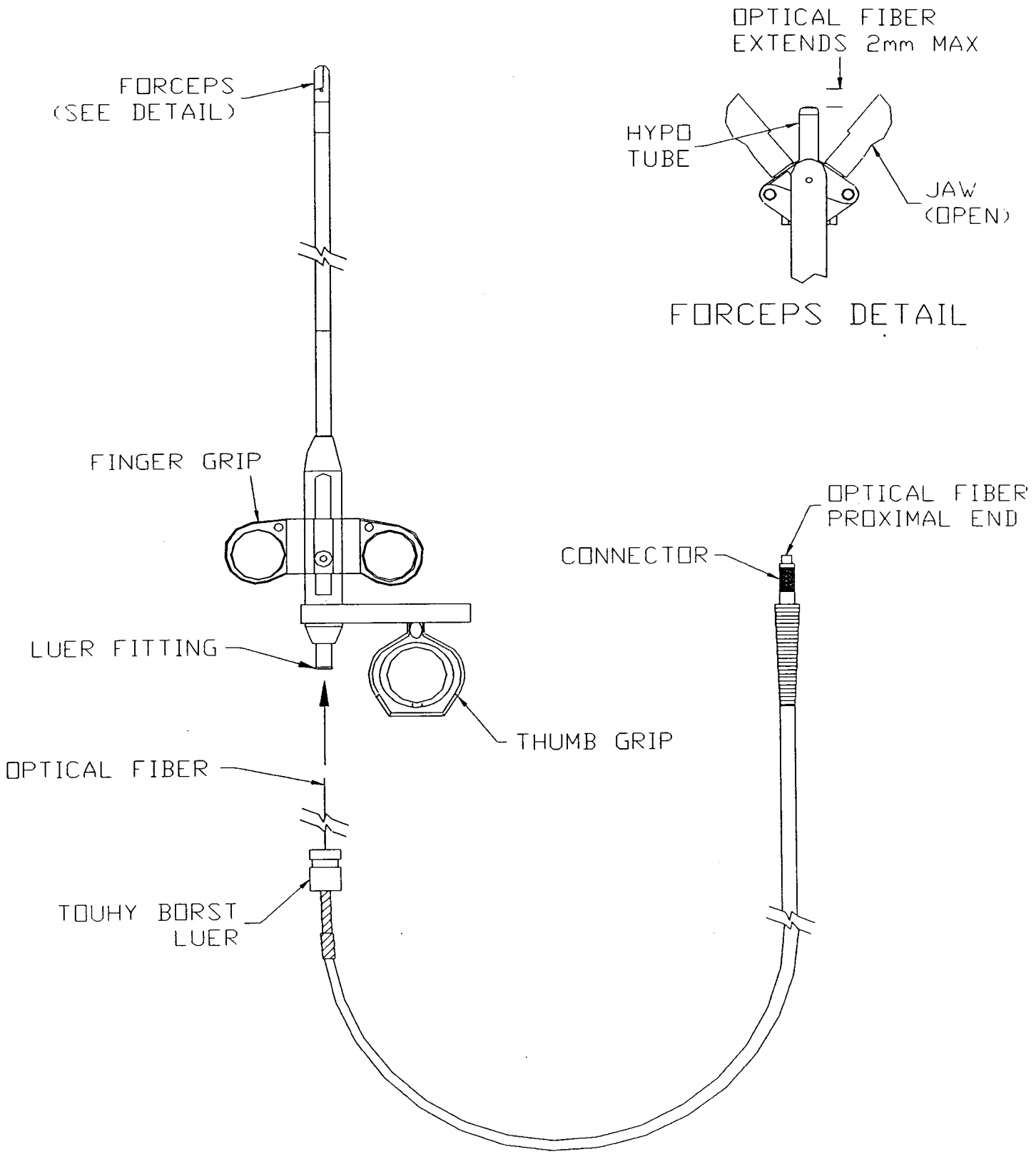
8.3.3 Fiber / Forceps assembly and setup

8.3.3.1 Insert the distal end of the optical biopsy fiber into the forceps until the distal end of the fiber extends a maximum of 2mm beyond the lumen (see detail in Figure 4, below).

8.3.3.2 Tighten the Touhy Borst luer onto the luer fitting at the proximal end of the forceps to lock the fiber in place.

8.3.3.3 As instructed in the message block of the system application insert the distal end of the forceps / optical fiber assembly into the BACKGROUND fixture on the front panel.

Figure 4 – Optical Fiber and Forceps


OPTICAL FIBER
EXTENDS 2mm MAX
FORCEPS
(SEE DETAIL)
HYPO
TUBE
JAW
(OPEN)
FORCEPS DETAIL
FINGER GRIP
OPTICAL FIBER
PROXIMAL END
CONNECTOR
LUER FITTING
THUMB GRIP
OPTICAL FIBER
TOUHY BORST
LUER

CAUTION

DO NOT INSERT A USED / CONTAMINATED FIBER INTO THE BACKGROUND FIXTURE.

8.3.3.3.1 Ensure that the forceps jaws are open and oriented vertically.

8.3.3.3.2 Insert until the jaws contact the stop.

8.3.3.4 As instructed in the message block, press the foot switch.

8.3.3.5 The status block will momentarily flash **ACQUIRING**; when the status block again reads **READY**, insert the distal end of the FORCEPS / OPTICAL FIBER assembly into the working channel of the endoscope. Proceed to section 8.3.5

8.3.4 Fiber and non-forceps accessory assembly and setup

8.3.4.1 Insert the distal end of the fiber into the proximal end of the device and complete assembly in accordance with accessory's instructions for use.

8.3.4.2 When instructed in the message block, insert the distal end of the optical fiber / accessory assembly into the BACKGROUND fixture.

8.3.4.2.1 Ensure that the fiber-end is exposed and unobstructed so that the light can be emitted into the fixture.

8.3.4.2.2 Insert until the device contacts the stop.

8.3.4.3 As instructed in the message block, press the foot switch.

8.3.4.4 The status block will momentarily flash **ACQUIRING**; when the status block again reads **READY** insert the distal end of the optical fiber / accessory assembly into the working channel of the endoscope.

NOTE: IF AT ANY TIME DURING A PROCEDURE IT IS NECESSARY TO CHANGE THE OPTICAL DEVICE, SELECT NEW DEVICE WITH THE F4 KEY OR THE TOUCHPAD, AND FOLLOW SECTIONS 8.3.2 THROUGH 8.3.4, ABOVE.

8.3.5 Normal Tissue Specimen Sample

WARNING: To properly use the device, you must obtain a spectral reading from the normal tissue specimen. The device cannot provide an evaluation without this information.

8.3.5.1 After a successful background the system is ready to acquire a spectral sample of normal tissue. The message block will read POSITION OPTICAL DEVICE ON NORMAL TISSUE. Place the distal end of the optical device in contact with the normal tissue to be tested and depress the foot switch.

8.3.5.2 The status block will momentarily flash **ACQUIRING.**

8.3.5.3 If the optical device was not in proper contact with the specimen, the status block will read **ERROR.** As indicated in the message block, simply reposition the optical fiber distal end and depress the foot switch.

8.3.5.4 Continue taking samples of the normal tissue (a minimum of 3 verified sequences) until the SELECT NEW SPECIMEN is displayed, and continue to the Polyp Tissue Specimen Acquisition section 8.3.6.

8.3.5.5 In the event of a suspect analysis of the normal tissue, a popup window will display:

> Normal tissue site may warrant further evaluation. After Normal Sample has been successfully collected, perform an Optical Biopsy of the original normal site to rule out the presence of suspect tissue.

8.3.5.6 Clear the popup window by selection OK, reposition the optical device on another normal site and repeat steps 8.3.5.1 through 8.3.5.5.

NOTES: 1) As indicated in the popup window, after a valid normal sample has been obtained, the suspect normal area should be retested as a specimen.

2) If a new background is obtained, another normal sample will be required

8.3.6 Polyp Tissue Specimen Acquisition

8.3.6.1 Select NEW SPECIMEN with the F3 key or the touchpad.

8.3.6.2 Place the distal end of the optical device in contact with the tissue to be tested and depress the foot switch.

8.3.6.3 The status block will momentarily flash **ACQUIRING.**

8.3.6.4 If the optical fiber was not in contact with the specimen, the status block will read **ERROR.** As indicated in the message block, simply reposition the optical fiber distal end and depress the foot switch.

8.3.6.5 Continue taking samples of the specimen until the analysis is displayed.

8.3.6.6 When ready to move to the next specimen, select NEW SPECIMEN with the F3 key or the touchpad. Continue collecting data as indicated in steps 8.3.6.1 through 8.3.6.4, above.

WARNING: To properly use the device, you must move the fiber to three different regions of the same polyp and obtain three distinct spectral measurements. The accuracy of the device to distinguish between "suspect" and "not suspect" polyps is dependent upon obtaining three distinct measurements from each polyp.

8.3.6.7 Once optical biopsy collection from a given patient is complete, select END PROCEDURE with the F5 key or the touchpad. As instructed in the message block, select END PROCEDURE again to terminate the current procedure, or press ESCAPE to return to the current procedure.

8.3.7 Post Procedure

8.3.7.1 Remove the optical fiber and forceps / accessory from the endoscope. See section 8.3.9 for disposition instructions.

8.3.7.2 The end procedure command closes and saves the procedure file to the internal hard drive and, if a disk is in the LS-120 drive, it archives the file to the LS-120 drive.

8.3.7.3 Disconnect the optical fiber connector from the system optical connector; replace the cap on the system optical connector.

8.3.7.4 To advance to the next procedure / patient, select BEGIN PROCEDURE with the F2 key or the touchpad or shut down the system with the ON / OFF switch. Close the cover.

8.3.8 Archiving of Data

8.3.8.1 If unarchived files remain on the hard drive, selecting ARCHIVE DATA will initiate the archiving process.

8.3.8.2 Files should be archived to the LS-120 drive on a regular basis (typically every two months).

8.3.8.3 No action besides archiving is required; the system is programmed to mark archived files and overwrite them as the hard drive approaches capacity.

8.3.9 Component Disposition

8.3.9.1 Dispose of the Optical Biopsy Fiber in accordance with applicable hospital regulations for disposal of bio-hazardous waste.

8.3.9.2 If the accessory forceps is used, clean and sterilize according to the respective manufacturer's instructions prior to reuse.

8.3.9.3 If another accessory is used, dispose in accordance with the manufacturer's Instructions for Use.

8.3.9.4 The Optical Biopsy™ System should be re-packaged in the original shipping crate and returned to SpectraScience, if service cannot be accomplished by SpectraScience at your facility.

8.3.10 Command Summary

COMMAND:	Use:
BEGIN PROCEDURE (F2)	Initiates the start of a procedure, including Optical Fiber setup and background calibration.
NEW SPECIMEN (F3)	Indicates that a new specimen will be sampled.
NEW FIBER(F4)	Initiates change to a new device; system initiates background calibration.
END PROCEDURE (F5)	Ends the data acquisition procedure for a given patient.
ARCHIVE DATA (F6)	Initiates saving of procedure data onto 120 Mbyte LS-120 drive.

8.3.11 Error Messages and Resolution

Error Message:	Resolution:
Reposition Optical Biopsy Fiber in Background / Reference Fixture	Reposition fiber in fixture; press foot switch After 5 attempts, replace optical biopsy fiber, position in background fixture, and depress footswitch; If still not successful after 5 more attempts, contact technical support
Foot pedal not connected	Connect foot pedal (foot switch) to rear of console
Signal Error, reposition Optical Biopsy Device	Fiber not in contact with specimen or movement occurred during acquisition; reposition and press foot switch
Replace Optical Biopsy Device	Disconnect Optical Biopsy replace with new device; See section 8.3.2, Optical Biopsy Fiber Setup
No media in drive	Insert disk in LS-120 drive
Contact technical support 100	Contact technical support
Contact technical support 110	Contact technical support
Contact technical support 120	Contact technical support
Startup Error 130	During startup - place cap on optical connector and restart system; During 2nd try - contact technical support
Startup Error 140	During startup - place cap on optical connector and restart system; During 2nd try - contact technical support

Startup Error 150	<u>During startup</u> - place cap on optical connector and restart system; <u>During 2nd try</u> - Contact technical support
Contact technical support 170	Contact technical support
Contact technical support 200	Contact Technical Support

Error Messages and Resolution (cont.)

Error Message:	Resolution:
Contact technical support 250	Contact technical support
Contact technical support 260	Contact technical support
Contact technical support 270	Contact technical support
Contact technical support 290	Contact technical support
Contact technical support 300	Contact technical support
Contact technical support 310	Contact technical support
Contact technical support 320	Contact technical support
Contact technical support 330	Contact technical support
Contact technical support 350	Contact technical support
Contact technical support 360	Contact technical support

8.4 Technical Support

8.4.1 Preventive inspection/maintenance will be performed every six (6) months by a manufacturer trained representative.

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

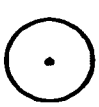
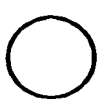
*Spectra*Science
14405 21st Ave. N., Suite 111
Minneapolis, Minnesota 55447 U.S.A.
Telephone: (612) 745-4120
Facsimile: (612) 745-4126

Authorized European Representative:
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

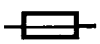
8.4.3 System Specifications

ITEM:	SPECIFICATION:	
CPU	200 MHz Pentium MMX™ single board	
Operating System	Windows® 95	
Electrical	USA / Canada	Europe
Voltage:	120 VAC / 60 Hz	230VAC / 50 Hz
Current:	3A (nominal)	1A (nominal)
Fuse:	4A, Type T, 250V	3A, Type T, 250V
Laser	337.1 nm Nitrogen Pulsed	
Repetition Rate	7.25 Hz	
Storage Temperature Range	-25°C to +50°C	
Operating Temperature Range	10°C to +40°C	
Relative Humidity Range	20% to 80%	
Atmospheric Pressure Range	700 hPa to 1060 hPa	
Weight	400lbs (approximately)	
Outside Dimensions (inches)	Height: 46.5 (from floor) Width: 26.5 (including handle) Depth: 19.5	
System Electrical Classification	Class I, type BF IPXO not for AP/APG or continuous use.	
Laser Safety Classification	Class I	

8.4.4 Glossary of System Symbols

Symbol	Meaning
	Alternating Current
	"Off" for only a part of equipment
	"On" for only a part of equipment
	Off (power disconnection from mains)
	On (power connection to mains)
	Type "BF" equipment

Non-ionizing radiation



Fuse

Attention, consult accompanying documents

Protective earth (ground)

8.4.4 Glossary of Definitions / Abbreviations

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.

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

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

Type F applied part is an applied 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).

IPXO (Ingress protection rating): no protection against moisture.

AP/APG:

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

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

Continuous Use:

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

9.0 DISCLAIMER OF WARRANTIES

*Spectra*Science, 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.

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

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