

PARKS FLO-LAB, OPERATING MANUAL



TYPE B APPLIED PART
MEDICAL EQUIPMENT



Class II Medical Device

THIS SYSTEM MEETS THE SAFETY REQUIREMENTS SPECIFIED FOR A CLASS II ACTIVE MEDICAL DEVICE ACCORDING TO IEC 61140

This device meets these Standards:



UL 60601-1 2003/04/25 ED: 1 Rev: 2006/04/26 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety.

PMEI's Quality System is ISO 13485:2016 Certified

This device must be plugged into a **120 Vac, 60 Hz, 'HOSPITAL ONLY' or 'HOSPITAL GRADE'** power outlet.

This device is manufactured by:



PARKS Medical Electronics, Inc.
19460 S.W. Shaw
Aloha, OR 97078 USA
Phone: 503-649-7007
Fax: 503-591-9753

Technical Support for the Parks Flo-Lab 1-888-356-9522

Monday - Friday 7:00 am to 3:30 pm Pacific Time



Mailing Address: P.O. Box 5669, Aloha, OR, 97006 USA
Shipping Address: 19460 SW Shaw, Aloha, OR 97078 USA
Fax: 503-591-9753 ~ e-mail: info@parksmed.com ~ Web Site: www.parksmed.com







INTRODUCTION

Thank you for choosing Parks Medical Electronics Computerized Flo-Lab. The Flo-Lab is a high performance, multi-function noninvasive vascular diagnostic system which utilizes today's most advanced technology to enable you to perform a variety of physiologic vascular examinations with greater accuracy and speed than ever before possible.

The Flo-Lab is the product of Parks Medical Electronics' over 30 years experience as a leader in production of vascular Doppler products, combined with feedback and input from users of our computerized vascular systems in hundreds of vascular laboratories worldwide since 1986. This system has a host of new features, many of which will be new to you, and we urge you to take the time to familiarize yourself with this manual to assure that you and your patients are getting the most out of your Flo-Lab.

OVERVIEW

The Parks Flo-Lab is a state-of-the-art instrument for the noninvasive physiologic assessment and diagnosis of peripheral vascular disease. This system combines all of the modalities needed to perform a broad range of vascular examinations, including:

- Doppler Evaluation (Arterial, Venous & Periorbital)

- Pulse Volume Recording (Arterial & Venous)

- Segmental Pressures

- Digital Pressures

- Post Exercise / Reactive Hyperemia

- Penile Pressures

- Digital Waveforms

- Venous Outflow (DVT)

- Reflux (Chronic Venous Insufficiency)

MULTI-FUNCTION SYSTEM

The Flo-Lab combines Parks directional Dopplers, bilateral Pulse Volume Recording (PVR), and bilateral Photoplethysmography in a compact, ergonomic package. The Flo-Lab features a highly advanced, micro-processor controlled, cuff inflation system, which provides a new degree of smoothness, accuracy and precision to blood pressure measurements. Other new features offered on the Flo-Lab include: a new multi-sensor wireless remote control; an optional automatic cuff selector (controlled by the computer); and an integrated Multi-Mode display to simplify the selection of Flo-Lab user options.

The Flo-Lab has been designed with one goal in mind, to assist the user in producing vascular studies with a greater degree of accuracy, in less time, than was ever before possible.

WARRANTY

Parks Medical Electronics, Inc., warrants this Doppler Product against defects in materials and workmanship for a period of two years, one year for probes, 90 days for cuffs. Parks will, at its discretion, replace or repair free of charge, including labor and shipping, all parts to be defective and subject to such warranty.

This warranty does not apply to any instrument or probe not used according to instructions or damaged by abuse, accident, alteration, misuse, and/or tampering.



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WARNINGS / HAZARDS

WARNING: MISUSE OF THIS EQUIPMENT AND INAPPROPRIATE ELECTRICAL CONNECTIONS WILL CREATE A SHOCK HAZARD. What appears to be simple connections to other equipment can place the patient and/or the operator at risk of electrical shock. **DO NOT** connect to an amplifier or intercom system. **DO NOT** connect items which are not specified as part of the original system.

FOLLOW THE MANUAL INSTRUCTIONS ON THE USE OF THIS EQUIPMENT. Avoid use involving electrical contact with other equipment. We assume no responsibility for misuse of our equipment.



WARNING: THE DRAWERS OF THIS UNIT ARE NOT SUITABLE TO USE AS A STEP OR FOR STANDING. These actions may cause the unit to tip and could result in physical injury.

WARNING: The multiple socket outlets of the power supply shall only be used for supplying power to equipment which is intended to form part of the system. Additional portable multiple socket outlets or extension cords shall not be connected to the system.

Power for the non-medical equipment supplied with the system (computer, monitor & printer) is intended to be supplied via the multiple socket outlets of the medical grade transformer supplied with the system. Plugging the non-medical equipment directly to wall power will compromise electrical safety and place the patient and/or the operator at risk of electrical shock.

WARNING: THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANAESTHETIC MIXTURES WITH AIR, OXYGEN OR NITROUS OXIDE. The possibility of explosion or fire always exists when this equipment is used in such an environment.

THIS EQUIPMENT SHOULD NOT BE USED WITH A DEFIBRILLATOR.

POTENTIAL ELECTROMAGNETIC OR OTHER INTERFERENCE: This Doppler may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Doppler, or shielding the location.

The Flo-Lab's IR remote receiver may respond to other IR equipment in the user's facility, which can interfere with the function of the Flo-Lab. If you suspect this is occurring, please contact Parks Technical Support at 1-888-356-9522. You may be provided with a corded remote to prevent further occurrences.

SUSCEPTIBILITY: This Doppler may experience a high pitched tone or buzzing noise from radio interference caused by a cell phone, mobile service or police station nearby. Interference may also be experienced from another Doppler, electrocautery or other sparking device, as well as defective fluorescent light fixtures or neon signs, if located in the close proximity.

INSPECT THE PROBE: Before using the probe, inspect for any cracks or breaks in the protective material covering the probe that could allow for ingress of conductive fluids such as acoustical coupling gel. Damage to the protective covering could create a shock or burn hazard if an uninsulated instrument is grounded and used with or touches other electronic equipment.

PHYSIOLOGICAL EFFECTS OF ULTRASOUND

IMPLANTED DEVICES

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections and as a precaution; avoid using ultrasound close to these.

STUDIES NEAR SENSITIVE TISSUES

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina. Similarly, extreme care should be taken near other sensitive nervous tissue. Based on experimental and epidemiological data, there is presently no identified risk associated with diagnostic ultrasound. However, a prudent and conservative approach is recommended in which diagnostic ultrasound should be used only for medical benefit and with minimal exposure.

THIS DOPPLER IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY.

ENVIRONMENTAL HAZARDS

There are no potential environmental hazards from the gels used with the probes.



WARNINGS / HAZARDS

WARNING: To avoid a tripping hazard and unnecessary damage, cables and hoses should be stored in the appropriate holders or cord wraps when not in use.

WARNING: Do not pull on cables and hoses to avoid unnecessary damage.

WARNING: PVR wave forms are subject to artifact due to room vibrations caused by air conditioning units, electric beds, treadmills and other electronic devices

WARNING: Front wheel brakes should be applied when the device is on an uneven surface.

WARNING: Use care with liquids in the vicinity of this device.

WARNING: The use of a non-shielded network cable may cause audible interference and artifact of Doppler wave form.

WARNING: To prevent hearing damage, make sure the Doppler volume is at a comfortable level when using headphones.

WARNING: Contraindication suggests that instrument not to be used for patients with blood clots or DVT if this is a known condition.

WARNING: Contraindication suggests that instrument not to be used for patients with recent surgery, ulcers, casts, or bandages that cannot or should not be compressed by pressure cuffs.

WARNING: Contraindication suggests that instrument not be used for patients who are post interventional procedure, IE, stent placement, arterial bypass graph.

WARNING: Contraindication suggests that instrument not to be used for patients with functioning dialysis access graph.



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SPECIFICATIONS



DOPPLER

Pencil Probes: High frequency (nominal 8 MHz).
Low frequency (nominal 4 MHz).

The exact frequencies of the instrument are indicated by a label attached to the probe cable. Be sure to reorder replacement probes by these frequencies. DO NOT remove the label attached to the probe cable.

Output Filter: User selectable for 28, 14, 7 & 3.5 (Hz).
Output Select: User selectable for normal or inverted recording.
Headphones: Standard low-impedance stereo headphones.

PLETHYSMOGRAPH

PVR: Pneumoplethysmograph (pulse volume recording).
PPG: Photoplethysmograph.
Sensor, Parks part # 832-8002-00.
Modes: AC coupled (arterial mode pulsations only).
DC coupled (venous mode gross volume changes).
Calibration: PPG - none.
PVR - user selectable calibrated pulse volume measurement.
Pressure ± 2 mm @ 100 mm Hg, ± 5 mm above 100 mm Hg.

CUFF INFLATOR

Inflate modes: Momentary (BP mode) or fill to preset (PVR mode).
Inflator Preset: User selectable.
Inflation Rate: BP mode - Linear, variable speed, user selectable 5-30 mm Hg/sec.
PVR mode - fixed 30 mm Hg/sec.
BP Bleed rate: User selectable 1-10 mm Hg/sec.
Valve type: Variable flow & solenoid activated.
Verification/Calibration: Cuff volume verification/calibration every 1000 hours or once a year.
Volume $\pm 2\%$.

REMOTE CONTROL

Functions: 22 button, 2.4GHz radio signal remote for volume, position, size, mute, trace auto scale, cuff inflator and deflator, freeze, save, escape, invert, enter and four direction cursors.

PHYSICAL

Height:	56 inches.	142 cm.
Width:	22 1/2 inches.	57 cm.
Depth:	31 inches.	78.7 cm.
Weight:	117 pounds.	60.66 kg.



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SPECIFICATIONS



ELECTRICAL

2110 Isolation	120 Vac, 60 Hz.
Power Supply:	3 amps. Typical, 5 amps. Peak @ 120 Vac The POWER cord must be plugged into a ' HOSPITAL ONLY ' or ' HOSPITAL GRADE ' alternating current power outlet.
19-B IR Remote	
Batteries:	3 AAA alkaline, Parks part # 854-0001-00.
Multi Port Inflator	12 Volt, 3.4 amps. Max current draw 1.2 amp
Power Supply:	Receives power from 2110 Isolation Power supply.

ENVIRONMENTAL CONDITIONS FOR TRANSPORT AND STORAGE

Ambient temperature:	Range, -40° F to 158° F (-40° C to +70° C).
Relative humidity:	10% to 95%, non-condensing.
Atmospheric Pressure:	Range, 500 hPa to 1060 hPa.

OPERATING CONDITIONS

IPXO rating:	Degree of protection against ingress of water none provided.
Temperature range:	50° F to 104° F (10° C to 40° C).
Heat generated:	1706 BTU per hour.

MAINTENANCE & CLEANING

The Flo-Lab operator should see "MAINTENANCE" in the APPENDICES section of this manual.

Repair and Maintenance Literature is also located in PARKS '**Bioengineering Manual**'. Circuit diagrams, component part lists, descriptions, calibration instructions, and other information are supplied to assist qualified technical personnel to repair parts of equipment which are designated by the manufacturer as repairable.

Calibrate every 1000 hours or once a year.

See PARKS '**Bioengineering Manual**' for Cuff Volume Verification/Calibration.

For information on setting up, operating and servicing the computer and printer supplied with the Flo-Lab, see the '**Owners Manual**' or '**Users Guide**' supplied by the manufacturer of that equipment. These manuals or guides were included with the Flo-Lab when it was purchased.

Turn off power and unplug instrument from wall outlet before cleaning. Loose dust accumulated on the outside of the instrument can be removed with a soft cloth or small paint brush. Dirt which remains can be removed with a soft cloth dampened in a mild solution of detergent and water. Abrasive cleaners should not be used.

DRAWERS

Top Drawer: 14.75" x 12.75" x 1.5"
(Maximum weight limit 4lbs)

Bottom Drawers (x2): 15.5" x 17.5" x 3.75"
(Maximum weight limit 12lbs)

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SPECIFICATIONS



FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

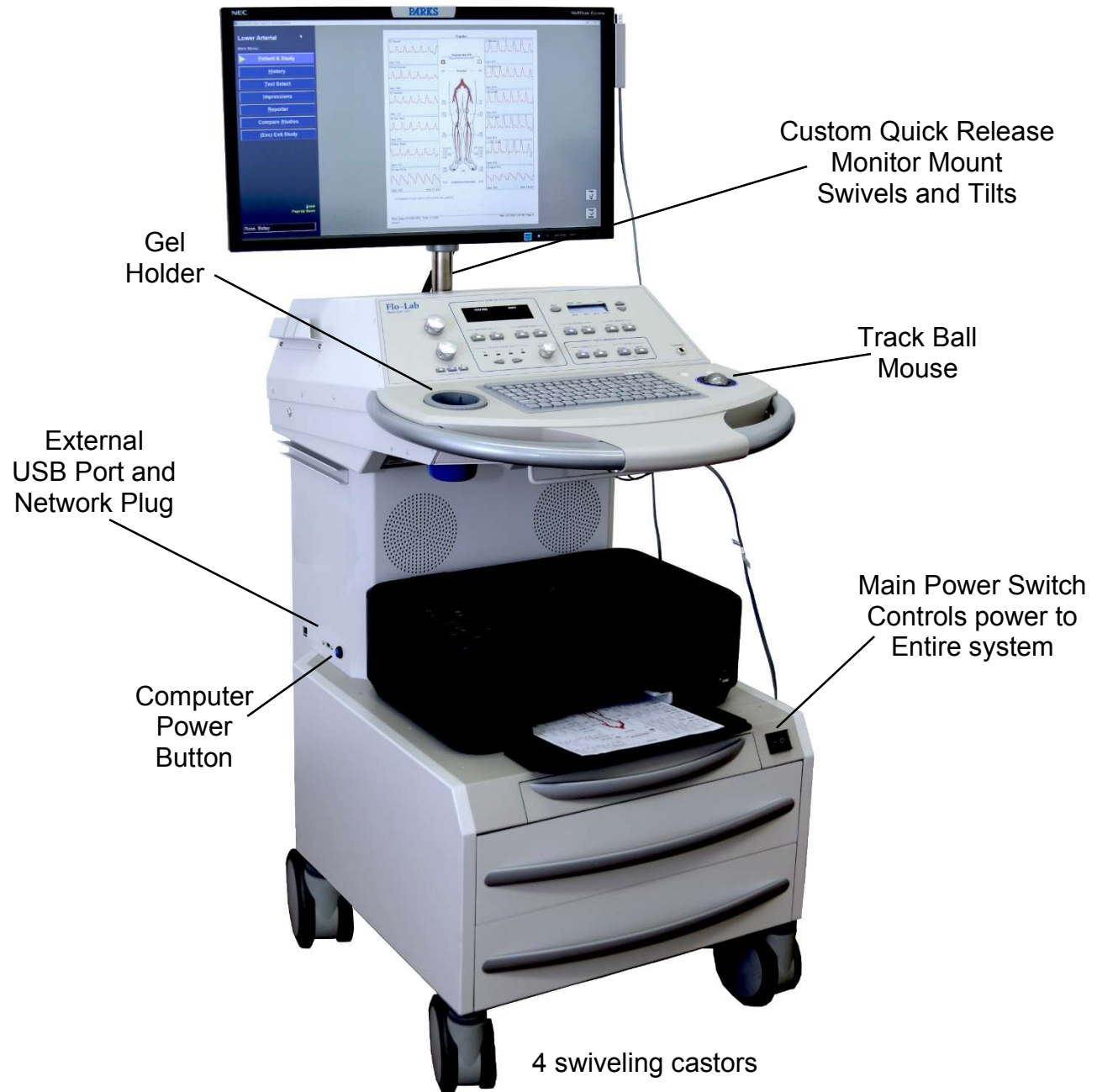
FCC Radiation Exposure Statement

To comply with FCC RF exposure compliance requirements, please use the supplied belt clips provided by the manufacturer. This device must not be co-located or operation in conjunction with any other antenna or transmitter except complying with FCC multi-transmitter requirements. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.



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INSTRUMENT VIEWS FRONT



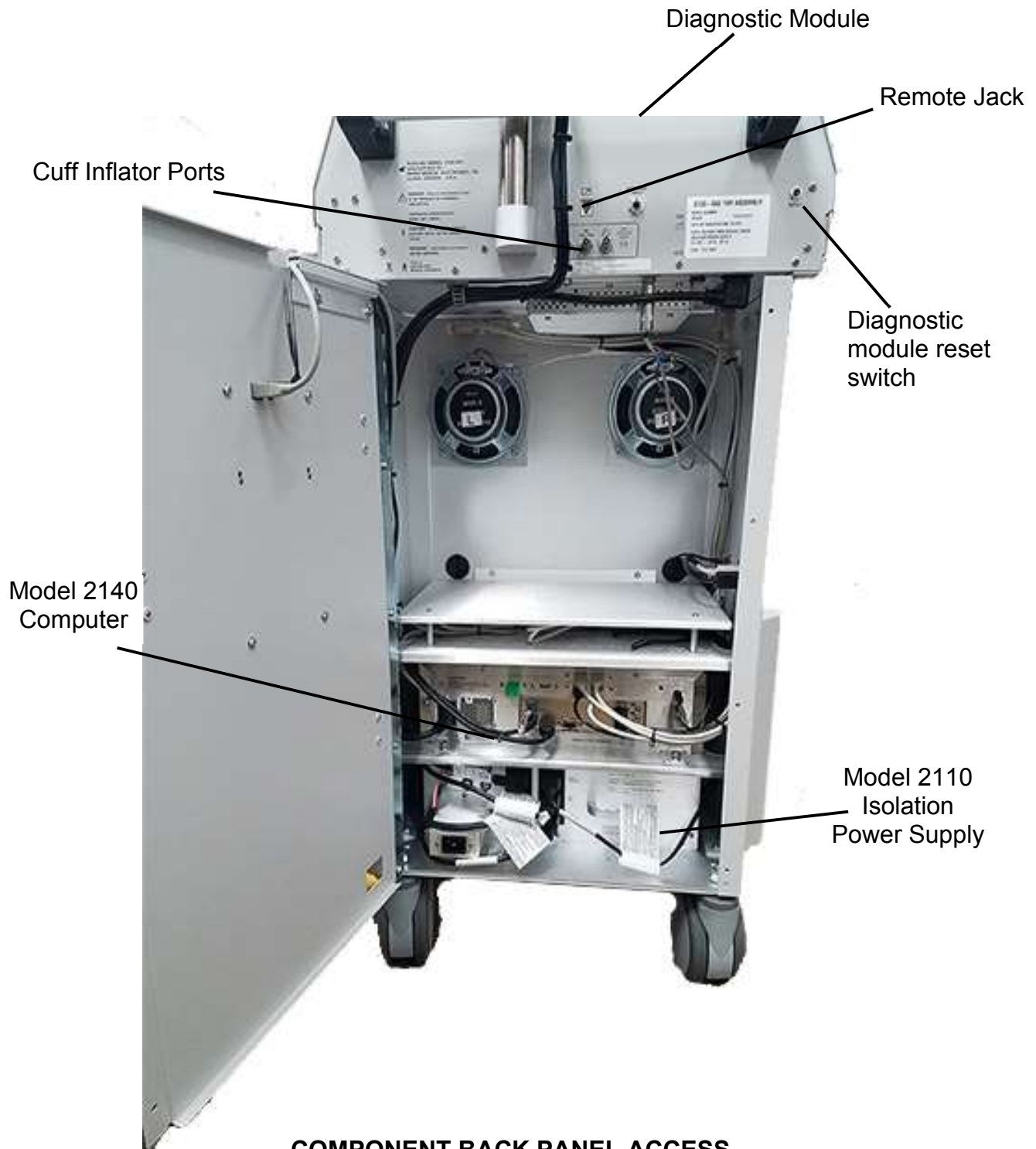
The Flo-Lab is furnished with a built-in isolated medical grade power supply. It must be plugged into a **120 Vac ~ 60 Hz** 'HOSPITAL ONLY' or 'HOSPITAL GRADE' power outlet via the external power cord. All power for the equipment furnished with the system must be supplied via the medical grade power supply. Plugging any equipment furnished with the system directly to wall power will compromise electrical safety.

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INSTRUMENT VIEWS

BACK



COMPONENT BACK PANEL ACCESS

Back door secured with four screws





SETUP

With the system purchase, a representative of Parks Medical Electronics will visit your facility to assist in setting up the new Flo-Lab vascular system. Generally, it is preferred that the customer leave the instrument in its original shipping containers until the representative arrives on-site to perform the installation. With facility space limitations, this is not always practical. Setup instructions are also included in PARKS '**Bioengineering Manual**'.

The following steps outline the process your Parks representative will go through in preparing the Flo-Lab for patient studies, and may be helpful should the need ever arise to reship the Flo-Lab to a different facility.

A. UNPACKING THE FLO-LAB

The Flo-Lab is, for the most part, fully assembled at the factory and delivered nearly "ready to go". Though thoroughly tested at the factory as a complete system, prior to shipment the display monitor and color printer are removed and repackaged in their original containers for shipment. The Flo-Lab is then crated in its custom container, with all accessories stored within the drawers of the Flo-Lab cart.

After the Flo-Lab, the display monitor, and printer are removed from their shipping cartons at the customer's facility, these containers should be stored, if possible, for future use.

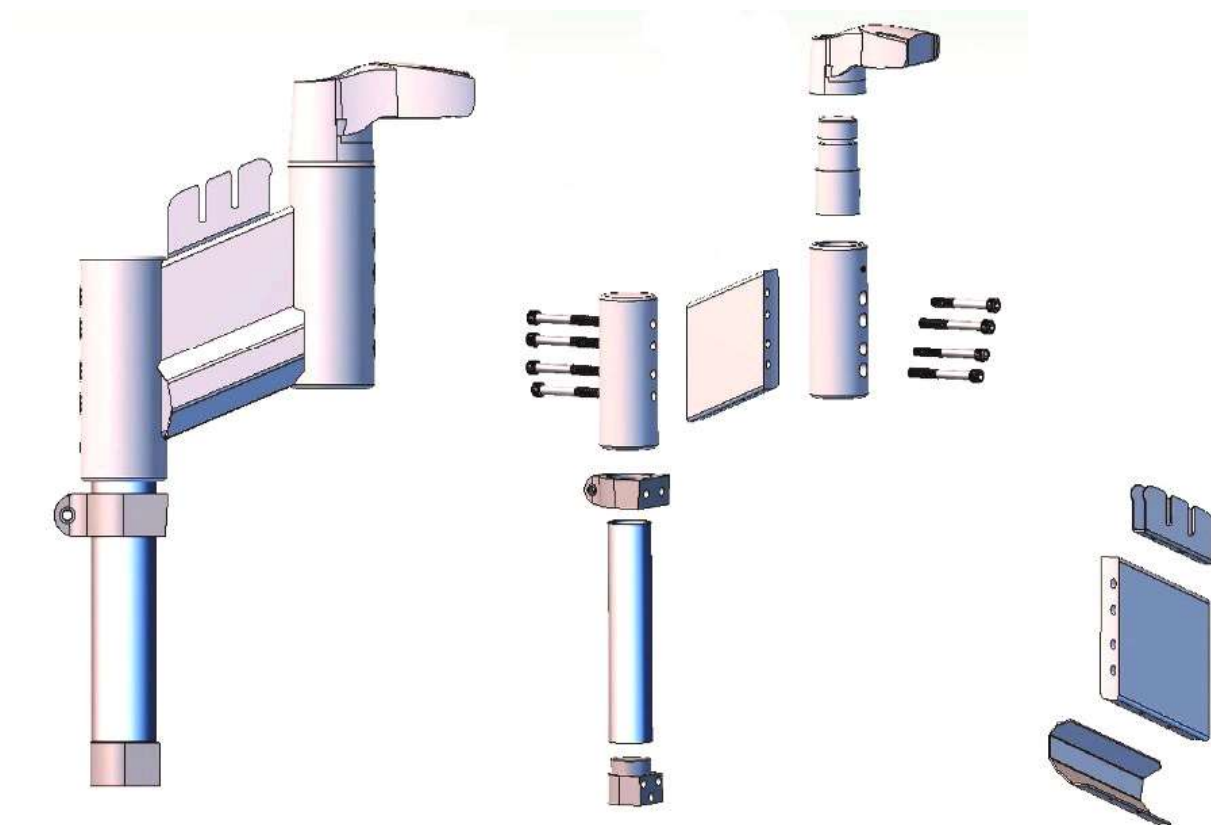
B. INSTALLING THE PRINTER

The printer power cord and the printer cable are pre-installed in the Flo-Lab cart to ease installation. Once the printer has been removed from its carton, it may be placed on the printer shelf below the Flo-Lab, and the cables attached. Locate the printer information packet (shipped in one of the cart drawers) if you would like detailed information about setting up the printer, paper loading, and loading/replacing ink cartridges.



C. MONITOR MOUNTING BRACKET/CONNECTING THE MONITOR

The custom monitor mounting bracket tilts swivels and rotates for comfortable, ergonomic use. Upon arrival, the base of the bracket will be mounted to the back of the Flo-Lab.



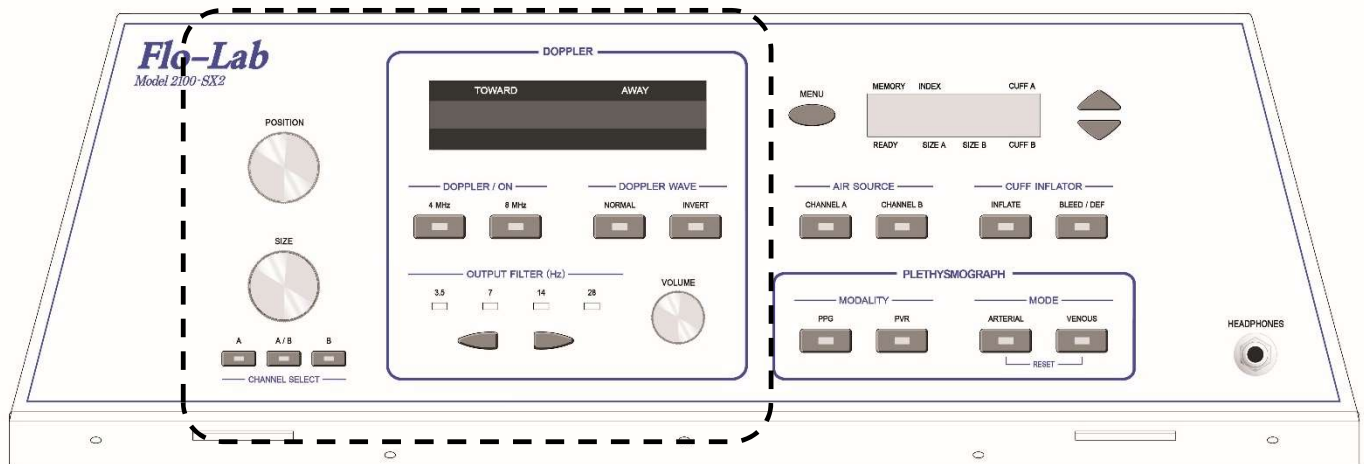
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DESCRIPTION OF CONTROLS

FRONT PANEL

A. DOPPLER SECTION



POSITION

This knob positions the waveform baseline up or down on the paper and monitor. This is a speed sensitive control, with a rapid turn of the knob making large, coarse changes in baseline position, while slow rotation of the position knob serves to make small or fine adjustments in baseline position.

SIZE

This knob changes the sensitivity, or gain of the instrument, allowing changes in waveform size (amplitude), or size, on the monitor. Size may be adjusted by the user at any time to increase or decrease the height of the waveforms, or may be adjusted to a "Preset" size factor prior to beginning testing (see Menu Display; Size Settings).

See page III . 30 in the appendices for techniques on better Doppler recordings.

CHANNEL SELECT (A, A/B, B)

When in bi-lateral mode (PVR or PPG), Channel Select allows the **SIZE** and **POSITION** to be set together or individually set.

A/B -- Adjusts the size or position for both A and B channels.

A – Adjusts the A channel size and position only.

B – Adjusts the B channel size and position only.

FLOW BAR GRAPH

Provides a display of Doppler signals, indicating both blood flow direction (relative to the probe) and relative blood flow velocities.

TOWARD

Display indicates flow Toward probe.

AWAY

Display indicates flow Away from probe.

DOPPLER / ON

If the Doppler is inactive, depressing either the 4MHz or 8MHz buttons activates the Doppler on the Flo-Lab with Doppler signal being displayed on monitor (if in a waveform screen) the active Doppler frequency (4 MHz or 8 MHz) will default to the last setting used. Plethysmographic modalities (PPG & PVR), if active, are automatically turned off.

4 MHZ

Light indicates nominal 4 MHz. The lower frequency is for deep vessels.

8 MHZ

Light indicates nominal 8 MHz. The higher frequency is for normal tests.



DESCRIPTION OF CONTROLS

FRONT PANEL

DOPPLER RECORDING

Pressing these buttons switch the recorder waveform to either normal or inverted orientation.

NORMAL

Flow toward the probe - Above

Flow away from probe - Below

INVERT

Flow toward the probe - Below

Flow away from probe - Above

OUTPUT FILTER - HZ

This control affects the smoothing of the recorded wave. It has no effect on what you hear. The numbers refer to the upper-frequency band pass of a 4-pole active filter. Higher numbers mean less smoothing but a more accurate reproduction of velocity changes. As you smooth the waveform by going to lower numbers, you are throwing away information. **Most recording is done using 3.5 Hz or 7 Hz.** This will reduce most unwanted noises and still render a good recordable signal.

3.5 Hz - Some detail and very smooth. **7 Hz** - Smoothed and detailed.

14 Hz - Some smoothing with more detail. **28 Hz** - Maximum detail.

- ◀ Left arrow (Decrease frequency button) steps to **more smoothing** and less detail.
- ▶ Right arrow (Increase frequency button) steps to **less smoothing** and more detail.

Refer to the “Basics” section in the Appendices (chapter V).

See page **III . 25** in the Appendices for technical articles on “Using Probes”.

VOLUME

Knob adjusts loudness.

Refer to the “Basics” section in the Appendices (chapter V).

See page **III . 25** in the Appendices for technical articles on “Using Probes”.

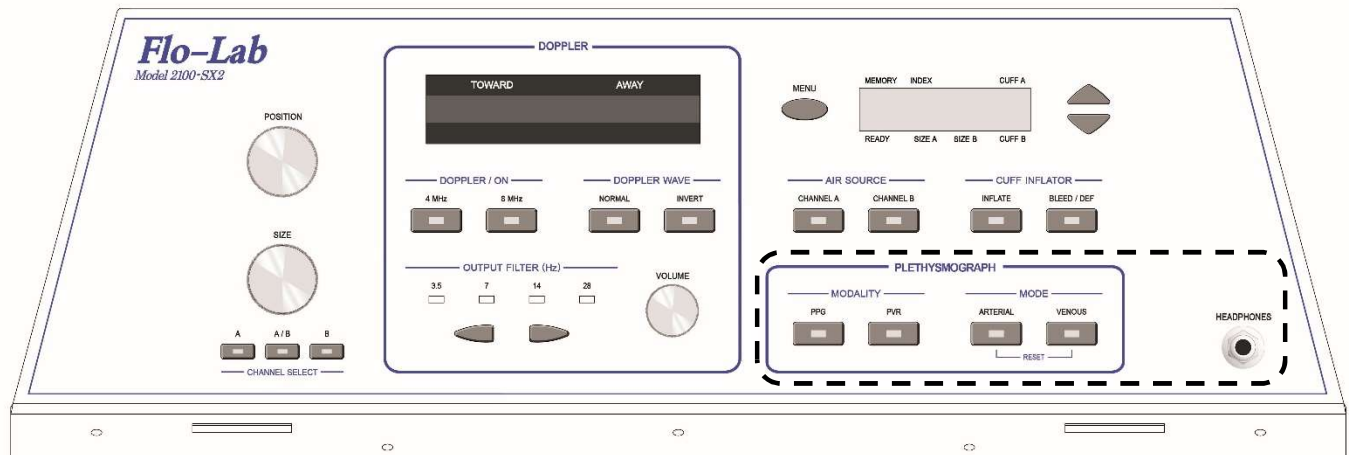


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DESCRIPTION OF CONTROLS FRONT PANEL

B. PLETHYSMOGRAPH SECTION



PPG

This button indicates, when illuminated, that the Photoplethysmograph is active, and that PPG signals will be displayed on the monitor. Pressing this button activates the PPG, and automatically deactivates the Doppler or PVR (if active).

See page **V.27** in the Appendices for technical articles on “Using Probes”.

PVR

Indicates, when illuminated, that the Pulse Volume Recorder is active, and that PVR signals will be displayed on the monitor. Pressing this button activates the PVR, and automatically deactivates Doppler or PPG (if active).

ARTERIAL

Indicates, when illuminated, that the instrument will display the plethysmographic (PPG or PVR) signals in Arterial, or “AC Coupled” mode. Pressing this button activates ARTERIAL mode and cancels VENOUS.

VENOUS

Indicates, when illuminated, that the instrument will display the plethysmographic (PPG or PVR) signals in Venous, or “DC Coupled” mode. Pressing this button activates VENOUS mode and cancels ARTERIAL.

RESET

In Arterial or Venous mode (active button light), pressing the button “zeros”, or “readies” PPG or PVR signal(s).

HEADPHONE JACK

This jack provides an output for low-impedance stereo headphones. When they are plugged in, the speaker is disconnected. You always hear more using headphones, especially when checking weak flow or veins.

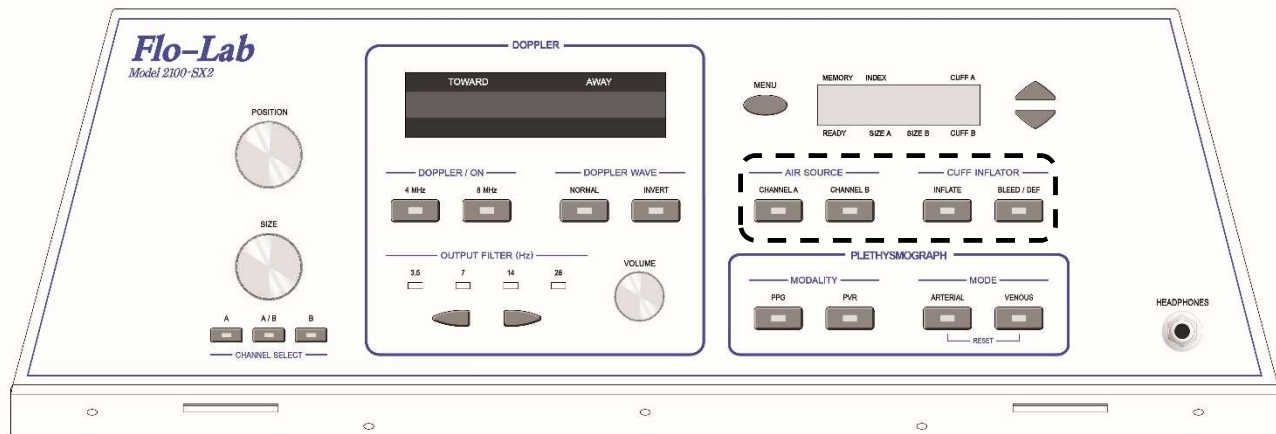
Note: In some cases an adapter is used to connect the headphones to the system. When they are not in use, the user must be careful to remove both the headphone jack and the adapter, to restore audible Doppler signals.

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DESCRIPTION OF CONTROLS FRONT PANEL

C. CUFF INFLATOR SECTION



AIR SOURCE

CHANNEL A

This cuff inflator hose button selects the A channel air source. This is used for all blood pressure measurements, and for right limb PVR recordings. Pressing this button alternately activates/deactivates this channel.

CHANNEL B

This hose button selects the B channel air source. This is used for left limb PVR recordings only. Pressing this button alternately activates/deactivates this channel.

CUFF INFLATOR

INFLATE

The cuff inflator button is mode sensitive, with different operation depending upon the mode selected. If Doppler or PPG is active, the instrument defaults to “Blood Pressure” mode, with the cuff inflating (pumping) as long as the button is held depressed. In PVR mode, the function changes, with a single press of the button automatically filling the cuff(s) to the desired preset pressure (see, ‘*Customizing your Flo-Lab; Multi-Mode Display; PVR Preset Pressures*’).

BLEED/DEF

This button is mode sensitive, with different operation depending upon the mode selected. In Doppler or PPG mode, with “Auto Bleed - OFF”, once the segmental or digit cuff is filled to the desired level, momentarily pressing the **BLEED/DEF** button activates a smooth, continuous bleed down of the pressure in the cuff at the selected bleed rate (see Customizing your Flo-Lab; Multi-Mode Display; Bleed Down Rate). While bleeding down, a second press of this button automatically rapidly deflates, or “dumps” the pressure in the cuff.

In “Auto Bleed - ON” mode (see, ‘*Customizing your Flo-Lab; Multi-Mode Display; Auto Bleed*’), the cuff will automatically begin to bleed when the inflation is completed. There is no need to press bleed/deflate to begin the bleed down process. In this mode, pressing **BLEED/DEF** provides a rapid deflate, or “dump” of the cuff pressure.

NOTE: For optimum performance of your Flo-Lab, use only the hoses furnished with the system. The calibration of cuff volume and volume change is based on using nine foot hoses and adapters as furnished. Any other length or size of tubing or addition of an in-line air chamber will cause the reported cuff volume to be increased or decreased by increase/decrease in volume.

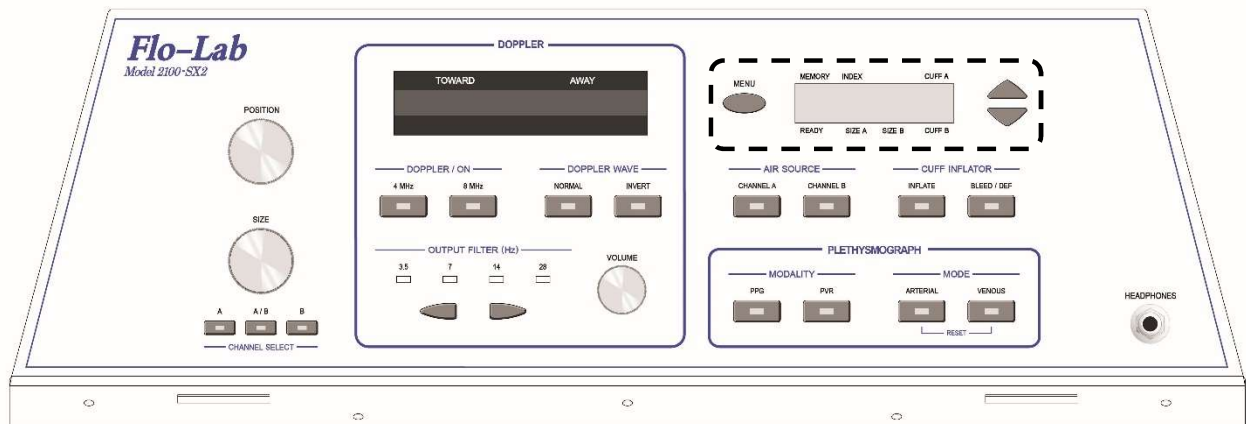


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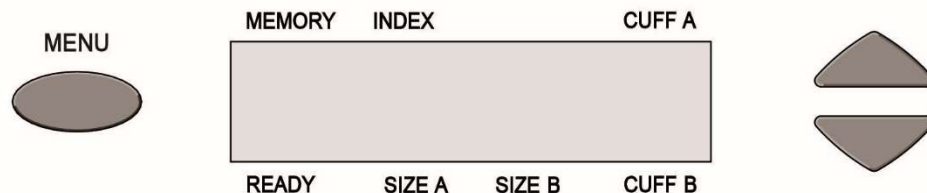


DESCRIPTION OF CONTROLS FRONT PANEL

D. DISPLAY SECTION



The Multi-Mode display is a multiple menu screen, allowing the user to quickly change operational/functional settings on the Flo-Lab. Below is an explanation of the Multi-Mode display control buttons, followed by a description of what each menu screen does, and how displayed parameters/settings may be changed.



MENU

This button cycles, with each press, through each of different menu screens (14 screens).

UP ARROW BUTTON

This button increases the displayed setting/parameter, or “toggles” the selection if that selection is of a “YES/NO” or “ON/OFF” type.

DOWN ARROW BUTTON

This button decreases the displayed setting/parameter, or “toggles” the selection if that selection is of a “YES/NO” or “ON/OFF” type.



DESCRIPTION OF CONTROLS FRONT PANEL

1. DEFAULT SCREEN

The Main Screen

The Main Screen is a Mode sensitive screen, with the top line differing slightly depending upon if the instrument is in PVR mode, or in DOPPLER or PPG mode (the top line is the same for DOPPLER and PPG modes).

2. MAIN SCREEN - PVR MODE

MEMORY	INDEX	CUFF A	
60<PRESET		0	
AB	0	0	0
READY	SIZE A	SIZE B	CUFF B

When PVR is active, the top line displays the “Preset Pressure”, which is the pressure the instrument will automatically fill PVR sensing cuff to. The Preset Pressure may be increased/decreased by pressing the UP and DOWN arrow buttons respectively, with the preset pressure changing in 5 mm Hg increments.

3. MAIN SCREEN - DOPPLER OR PPG MODE

MEMORY	INDEX	CUFF A	
1:132-1.13		0	
AB	0	0	0
READY	SIZE A	SIZE B	CUFF B

When either **DOPPLER** or **PPG** are selected, the top line displays Memory & Index. *Should the Flo-Lab be operated without a computer hookup*, the Flo-Lab has internal memory allowing the capture and saving of segmental blood pressures for later, and automatically calculates the corresponding “indices”, for manual transfer onto a form.

In this mode, the first position of the top line in the Multi-Mode Display is the Memory location label, with stored pressures and calculated indices appearing next to the location label. The first two memory locations are labeled **RB** and **LB** (for storing the Right and Left Brachial systolic blood pressures respectively), followed by labels of “1-18”, for storage of up to 18 additional blood pressures. As blood pressures are saved in memory slots 1-18, the instrument calculates and displays the saved pressures “Index” (compared to the highest saved brachial pressure). The UP and DOWN arrow buttons are used to cycle up and down through each memory location for review and/or transfer of data.





DESCRIPTION OF CONTROLS FRONT PANEL

4. MAIN SCREEN - STANDARD FUNCTIONS

MEMORY	INDEX	CUFF A	
60<PRESET		0	
AB	0	0	0
READY	SIZE A	SIZE B	CUFF B

SIZE Readout

SIZE A and **SIZE B** section of the Multi-Mode display Main Menu provide a digital readout of the size setting in use for any (PPG, PVR or DOPPLER) recording. The Size scale in use is 0 - 100 (%). A setting of 40, for example, means the Flo-Lab is recording at 40% of maximum gain instrument gain. **SIZE A** is for the A channel (normally the Right channel), **SIZE B** is for the B channel (normally the left channel). **SIZE A** is normally used for all Doppler recordings, as well as Right Channel PVR and PPG recordings. **SIZE B** indicates the size setting for Left Channel PVR and PPG recordings.

SIZE A and **SIZE B** are typically adjusted together (set to equal values) when performing bilateral recording, but may be separately set. To set Size A & B individually:

Deactivate the channel you do *not* want to change by pressing the corresponding button (**CHANNEL A** or **CHANNEL B**) so that its indicator light is off. Turning the **SIZE** knob will now change only the active (lit) channel Size setting.

The second channel may be adjusted in the same way, by deactivating the channel already set, activating the channel to be adjusted, and turning the **SIZE** knob. When each channel has been set to the desired level, both may now be switched back to active, with the system maintaining each channels individual size setting.

NOTE: Once both channels are active, turning the size knob further will always switch the Size setting back to "equal" - the B channel matching / equalizing to the A channel.

READY indicators

Ready indicators (the letters A & B, for the Right and Left channels respectively) appear when a Plethysmographic signal has been "zeroed" for display on the Monitor. In PPG, ARTERIAL mode, READY occurs automatically after the PPG sensor has been positioned on the patient. In PVR, Arterial mode, READY occurs automatically after the cuff pressure has stabilized/settled. When zero is achieved (usually within 5 seconds), the letters "A" and/or "B" will appear in the display window.

In "Venous Mode" the zeroing of the waveform is not automatic, and requires pressing the **VENOUS** button. This is normally pressed after the PPG sensor has been positioned, or the PVR cuff has been filled to a stable level. When the zeroing sequence is complete, the "A" and/or "B" READY Indicators will appear in the display window.

Cuff A & Cuff B Pressure

Cuff A and Cuff B displays the air pressure currently in each/either cuff channel. Blood pressure is always measured using channel A (either DOPPLER or PPG mode). Bilateral PVR recordings fill both the Right and Left channel cuff simultaneously, displaying each cuff pressure as CUFF A & CUFF B respectively.



DESCRIPTION OF CONTROLS FRONT PANEL

5. DESCRIPTION OF MENU SCREENS

SCREEN #1: PLETHYSMOGRAPH SETTLE TIME

Plethysmograph settle time allows the user to select the AC Mode “Auto-Zero Rate” applied to the displayed PVR & PPG waveforms - labeled as FAST, MEDIUM & SLOW (corresponding to how quickly the wave will re-stabilize itself). FAST provides the most stable waveform, but can alter some slower changing elements of the wave, resulting in wave distortion. Slow provides the most UN-affected (distortion free) waveform, but also shows a great deal of unwanted waveform “drift”, such as respiratory artifact. In general, where waveforms are being viewed but not recorded/analyzed (such as when viewing a PPG signal to determine a Digit blood pressure), the FAST works best. When recording PVR and PPG waveforms for analysis, SLOW or MEDIUM should be used to minimize the filtering effect on important waveform elements.

SCREEN #2: SIGNALS A & B ARE SWAPPED/NOT SWAPPED

There may be circumstances where it is desirable to display signals “swapped”, with channel A displaying the Left side signal (PPG or PVR), and channel B displaying the Right. In those instances, from this menu screen, pressing the **UP** or **DOWN** arrow buttons will toggle the selection.

SCREEN #3: CLEAR ALL INDICES

If the Flo-Lab memory locations built into the Multi-Mode Display have been used, pressing the **UP** or **DOWN** arrow buttons from this screen will clear all stored pressures and indices.

SCREEN #4: DUAL WAVEFORMS/SINGLE WAVEFORM

This controls how the strip chart recorder displays information (**If So Equipped**). When Single Waveform is selected, the strip chart recorder operates as a single, 40 mm wide strip chart. When Dual Waveform is selected, the recorder operates as a two-channel strip chart, with 20 mm wide charts.

SCREEN #5: EXTERNAL SIGNAL ON/OFF

The Flo-Lab provides an external input on the back panel to allow other compatible devices (such as Parks Penile PVR module) to be connected and displays its output information on the computer monitor. Pressing the **UP** or **DOWN** arrow buttons toggles between the selected active Flo-Lab signal (DOPPLER / PVR / PPG) and the external device signal.

SCREEN #6: BP SLOW FILL RATE

When taking blood pressure measurements, the Flo-Lab cuff inflator starts off at a preset inflation rate of 30 mm Hg/second. In an effort to minimize over-inflation (to reduce testing time and patient discomfort), the Flo-Lab may be set up to slow the cuff filling rate. This screen gives the user the option of having cuff filling slow down to any fill rate they desire. From this screen the **UP** and **DOWN** arrow buttons may be used to select any Slow Fill Rate between 1 & 30 mm Hg/second. For most users, setting this rate between 12 - 15 mm Hg per second appears to be optimum.

SCREEN #7: BP SLOW FILL START

Though it's possible to have the Slow Fill Rate setting affect the entire inflation range, it is far more efficient (time wise) to all let the inflator fill at the standard fast rate up to a certain point, and *then* slow down to the Slow Fill Rate. This screen allows the user to select the level at which the Slow Fill Rate will begin. From this screen, pressing the **UP** and **DOWN** arrow buttons increases/decreases the slow fill Start Point, in 5 mm Hg increments. Best results seem to be with this point set between 90-100 mm Hg.





DESCRIPTION OF CONTROLS FRONT PANEL

SCREEN #8: PVR CALIBRATION SEQUENCE ON/OFF

Users may elect to have the instrument calculate the pulse volume of PVR waveforms (in milliliters), or not. To choose to have the instrument make this calculation, turn PVR Calibration Sequence On, to not have the instrument calculate this information, choose PVR Calibration Sequence OFF. Pressing the **UP** and **DOWN** arrow buttons toggles between these two options.

SCREEN #9: PVR CAL A FACTOR

The instrument is provided with a Calibration Volume Chamber to verify the instrument is correctly measuring the cuff volume (a necessary component in the calculation of PVR waveform volume). This screen allows qualified personnel to adjust the displayed Channel A "calibration factor" until accurate volume measurement is achieved (Using the Calibration Volume Chamber). Refer to Bioengineering Manual.

SCREEN #10: PVR CAL B FACTOR

See Screen #9 above. This screen is used to adjust the Channel B calibration factor.

SCREEN #11: BLEED RATE

The user may select a bleed down rate that provides the best trade-off between measurement accuracy, and measurement time. The slower the bleed down rate, the more accurate and repeatable the pressure measurement will be. Too slow, however, may prove unnecessarily uncomfortable for the patient. Pressing the **UP** and **DOWN** arrow buttons will increase/decrease the bleed rate setting.

NOTE: AS A GENERAL RULE, the user should expect that there may be a blood pressure measurement error equal to the bleed rate setting (with a bleed rate setting of 3 mm Hg/sec, for example, blood pressure measurements may be off as much as 3 mm Hg). This error will be slightly less on patients with heart rates faster than 60, slightly more on patients with heart rates lower than 60. A setting of 2 - 4 mm Hg/sec is typically selected by users.

SCREEN #12: FIRMWARE VERSION

This screen displays the version of programming code used in the Multi-mode Display. It has no relation to the software version on the system main computer system.

SCREEN #13: AUTO BLEED ON/OFF

When taking blood pressure measurements, the user may choose to have the Flo-Lab begin cuff pressure bleed-down only *after* the **BLEED/DEF** button is pressed (Auto Bleed - Off), or to have the Flo-Lab begin bleed-down automatically after the **INFLATE** button is released (Auto Bleed - On). Pressing the **UP** and **DOWN** arrow buttons toggles between these options.

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DESCRIPTION OF CONTROLS LOWER FRONT PANEL



TRACKBALL

The trackball (mouse) manipulates your cursor when in Windows and the SonovaE software. Right Click button and left click button.

GEL HOLDER

Positioned to the left of the keyboard, the gel holder conveniently stores your gel bottles.





DESCRIPTION OF CONTROLS

LOWER FRONT PANEL UNDER THE PRINTER (FACING FLO-LAB)



MAIN POWER ON/OFF SWITCH

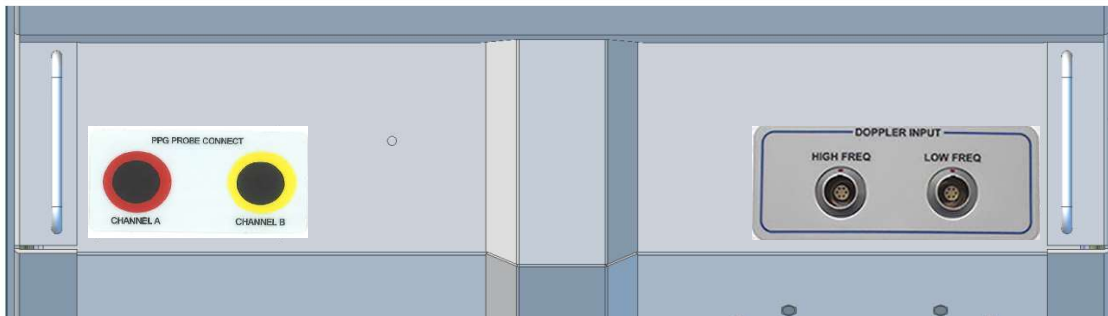
The main power on/off switch for the Flo-Lab is located on the lower right front of the cart directly under the printer shelf. This on/off button controls all power to the Flo-Lab, printer and monitor, through the built-in isolated medical grade power supply.

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DESCRIPTION OF CONTROLS

CABLE CONNECTION PANEL (UNDER KEYBOARD DECK)



PPG PROBE CONNECT JACKS

CHANNEL A -- Photoplethysmograph probe jack (patient's right side).

CHANNEL B -- Photoplethysmograph probe jack (patient's left side).

DOPPLER INPUT JACKS

HIGH FREQ -- Nominal 8 MHz DOPPLER probe jack.

LOW FREQ -- Nominal 4 MHz DOPPLER probe jack.

Connection of Doppler probes

The exact frequencies of the probes are indicated by a label attached to the probe cable. When ordering new probes, be sure to order these frequencies. **DO NOT** remove the label attached to the probe cable

The Doppler can be used with PARKS:

Standard high frequency (nominal 8 MHz) 3/8" (10 mm) diameter pencil probe.

Low frequency (nominal 4 MHz) 1/2" (12 mm) diameter pencil probe.

DO NOT POINT THE ULTRASONIC BEAM INTO THE RETINA OF THE EYE.

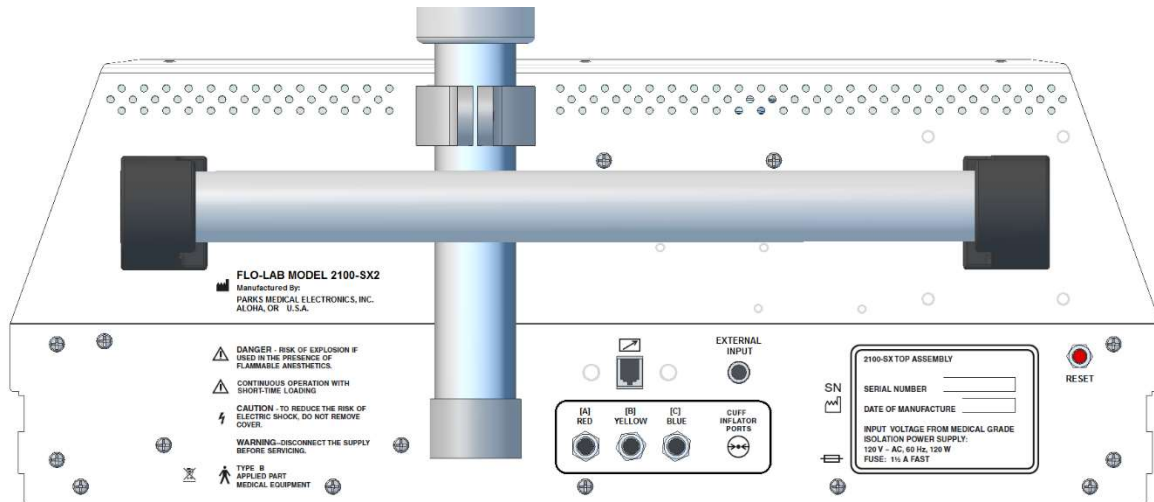
THIS INSTRUMENT IS DESIGNED ONLY FOR VASCULAR WORK, NOT OBSTETRICAL SERVICE.

TYPE B APPLIED PART MEDICAL EQUIPMENT

Defined as having adequate protection against electric shock; meets current leakage requirements. Suitable for external use, NOT suitable for direct cardiac applications.

PARKS FLO-LAB, OPERATING MANUAL

DESCRIPTION OF CONTROLS DIAGNOSTIC MODULE



DANGER: RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

CAUTION DANGEROUS VOLTAGE

Warning, no user serviceable parts inside. Refer servicing to qualified service personnel.

TYPE B APPLIED PART MEDICAL EQUIPMENT

Defined as having adequate protection against electric shock; meets current leakage requirements. Suitable for external use, NOT suitable for direct cardiac applications.

MODE OF OPERATION: CONTINUOUS OPERATION WITH SHORT-TIME LOADING.

The Air Pumps for the Blood Pressure Cuffs shall be operated for a **maximum of four minutes continuously** and then allowed to cool to ambient temperature, which will take 1½ hours.

CUFF INFLATOR PORTS

RED / CUFF A

(RED) HOSE CONNECTION PORT

YELLOW / CUFF B

(YELLOW) HOSE CONNECTION PORT

BLUE / CUFF C

(BLUE) HOSE CONNECTION PORT

REMOTE

Plug the infrared remote receiver (300-0277-00) into this jack.

FLO-LAB RESET

Very infrequently, the Flo-Lab may refuse to start. Use this RESET to clear the Flo-Lab without shutting down the entire system. However, **DO NOT** do so without first calling Technical Support toll free at 1-888-356-9522.





DESCRIPTION OF CONTROLS DIAGNOSTIC MODULE



SEPARATE COLLECTION FOR ELECTRICAL AND ELECTRONIC EQUIPMENT.

Old instruments should not be disposed of in land fills.



“ATTENTION, CONSULT ACCOMPANYING DOCUMENTS”

These statements on the back panel apply to the connections directly under them on the Bottom Back Panel.



SAFETY ISOLATING TRANSFORMER (POWER SUPPLY)

Built-in isolated medical grade transformer supplies power to the Flo-Lab when plugged into an appropriate “HOSPITAL GRADE” alternating current outlet.



ALTERNATING CURRENT

POWER INPUT must match the ratings printed on the POWER SUPPLY PANEL and the MAIN POWER CORD PANEL.

120 V ac ~, 60 HZ, 120VA



CAUTION DANGEROUS VOLTAGE

Unplug the unit from the wall outlet before replacing the FUSE.



FUSE

Fuse, 1½ AMPERE, FAST.

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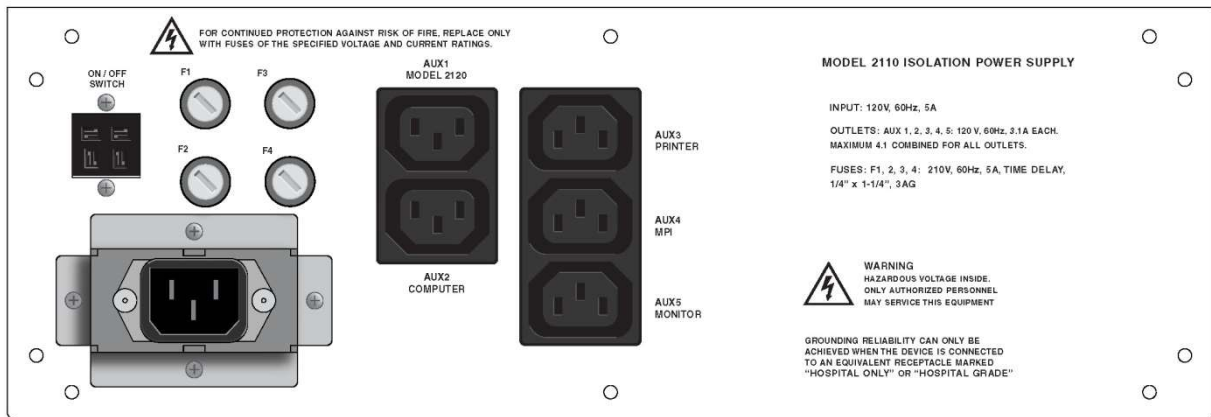
DESCRIPTION OF CONTROLS

2110 ISOLATION POWER SUPPLY

2110 Isolation E power supply is available for special power requirements of export units.

The Flo-Lab must be plugged into the outlet marked "Model 2120". Usage for other outlets must not exceed what is specified on the panel.

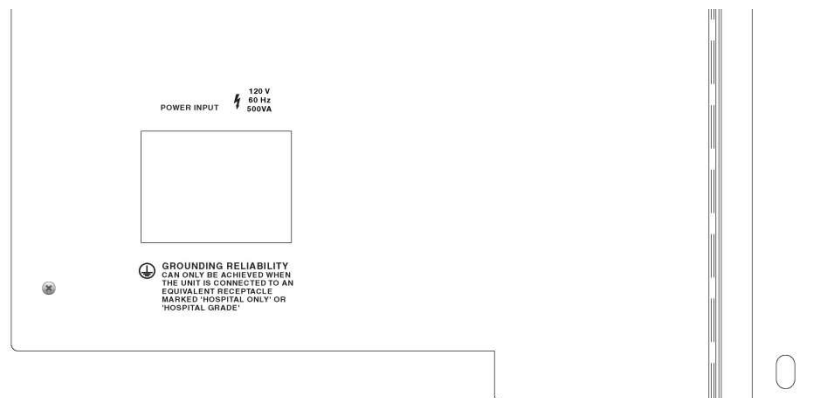
POWER INPUT must match the ratings printed on the POWER SUPPLY PANEL and MAIN POWER CORD PANEL.



 Safety isolating transformer

 Four fuses, 5 ampere, TYPE 313 SLOW (internal)

BACK DOOR (LEFT SIDE)



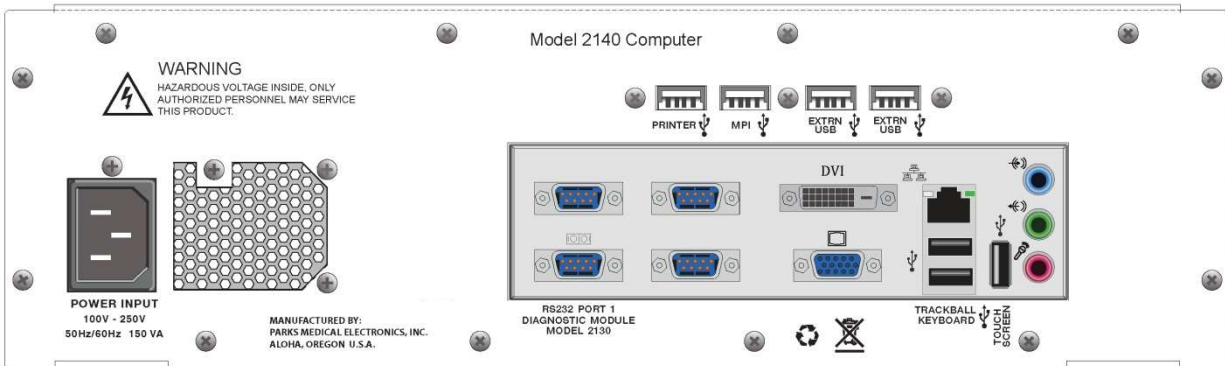
 Protective earth (ground)

 Dangerous voltage

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DESCRIPTION OF CONTROLS

2140 COMPUTER



NOTE: This illustration is intended as guidance. The appearance of your particular unit's back panel may vary depending upon when your unit was purchased.

POWER INPUT

Power cord connects from the 2110 Isolation Power Supply to the input.
100-250V, 50-60 Hz, 150 VA



USB PORTS

Connects peripheral devices to the computer (Printer, MPI, Monitor, Keyboard, Trackball, Optional Temperature sensor and the diagnostic module). Each USB port is labeled for its intended use for optimal ESD shielding.



Connection for the monitor.



RJ-45 network connection.

DVI

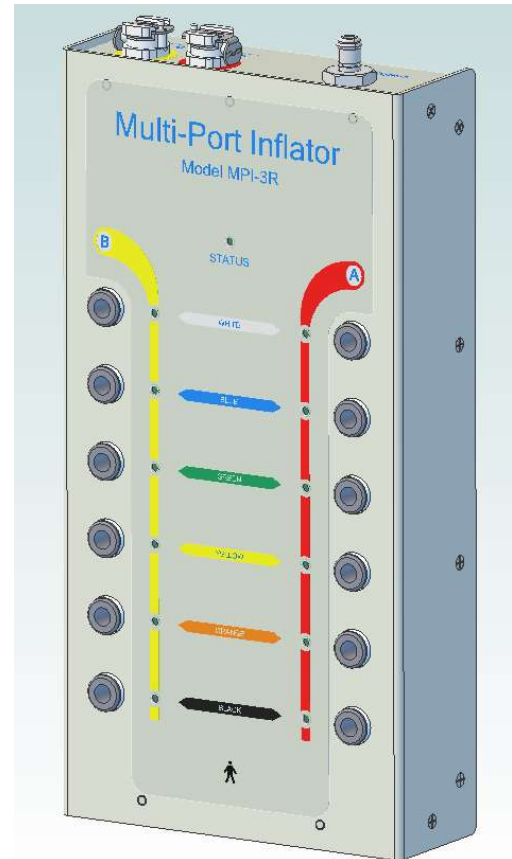
DVI video input.

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DESCRIPTION OF CONTROLS MULTI-PORT INFLATOR

OVERVIEW:

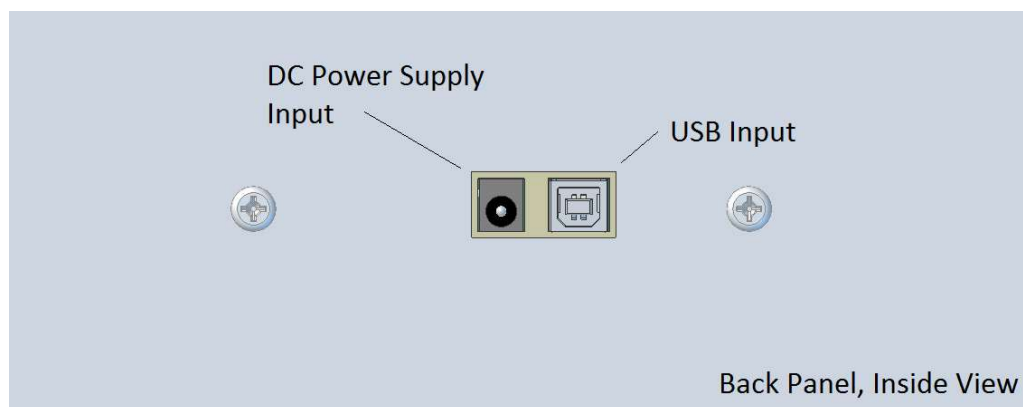
The Multiport Automatic Cuff Selector (MPI) is an optional module which connects to the two “Outlet” air hoses on the Flo-Lab. The MP then acts as a ‘switching hub’, automatically routing/connecting the Flo-Lab air/signal through any of 12 air hoses in the Red and Yellow bundles, or to the A Channel Bypass hose. Once connected, the MPI works in conjunction with Parks’ SonovaE software to provide automatic, hands-free selection of the appropriate blood pressure cuff(s), based on the study and test site(s) indicated on the Flo-Lab display screen.



MPI CONNECTIONS - ELECTRICAL

ELECTRICAL:

The MPI is externally mounted to the back panel of the Flo-Lab cart, with the two electrical connections (USB and DC Power) made through the cart door, accessible only when the cart rear door is open.



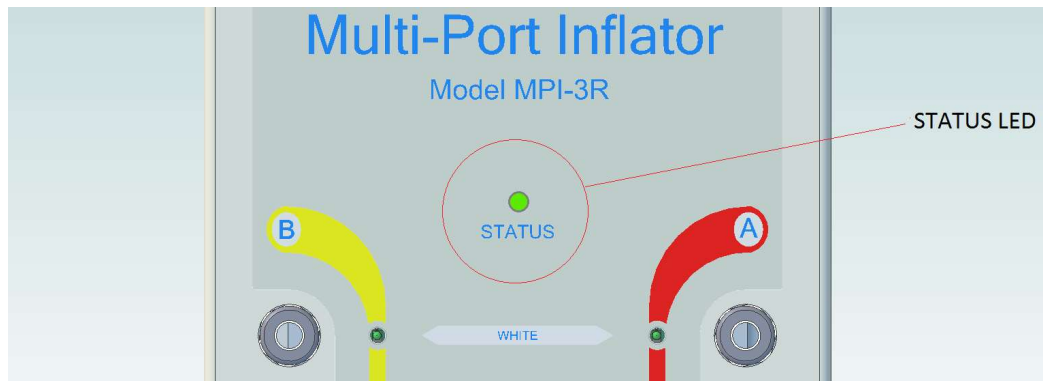
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DESCRIPTION OF CONTROLS MULTI-PORT INFLATOR

STATUS LED:

The MPI is equipped with a Status LED to help aid in trouble-shooting issues with the MPI.



The STATUS LED remains off when there are no connections or no power to the MPI. When the Flo-Lab is turned on, the following LED colors indicated the listed Status/Condition:

STEADY RED – Indicates the MPI is connected to its DC Power Supply.

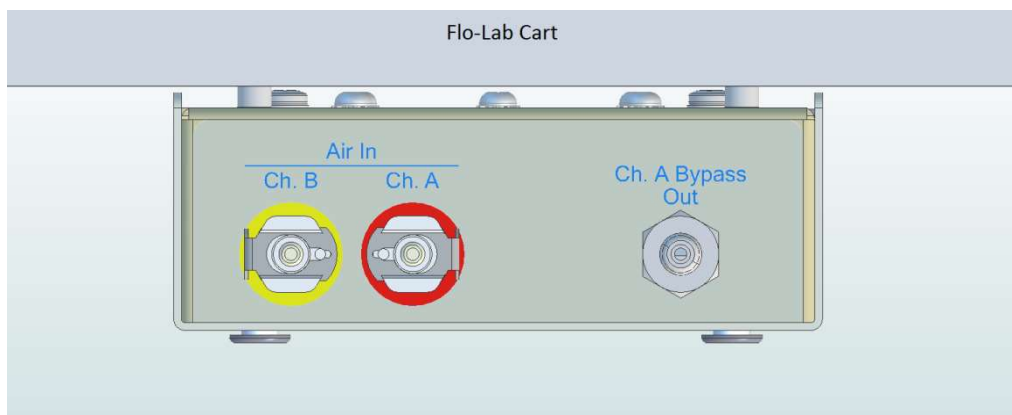
STEADY GREEN – Indicates the MPI is both connected to its DC Power AND is connected to an active USB connection.

FLASHING GREEN - Indicates both the DC Power and USB cable are connected, and Data is being transferred/received.

MPI CONNECTIONS - PNEUMATIC

PNEUMATIC INPUT

The MPI air inputs, marked “Air In” are located on the upper end panel of the MPI, color coded Red and Yellow to correspond to the Flo-Lab A (Red) and Yellow (B) output air channels.





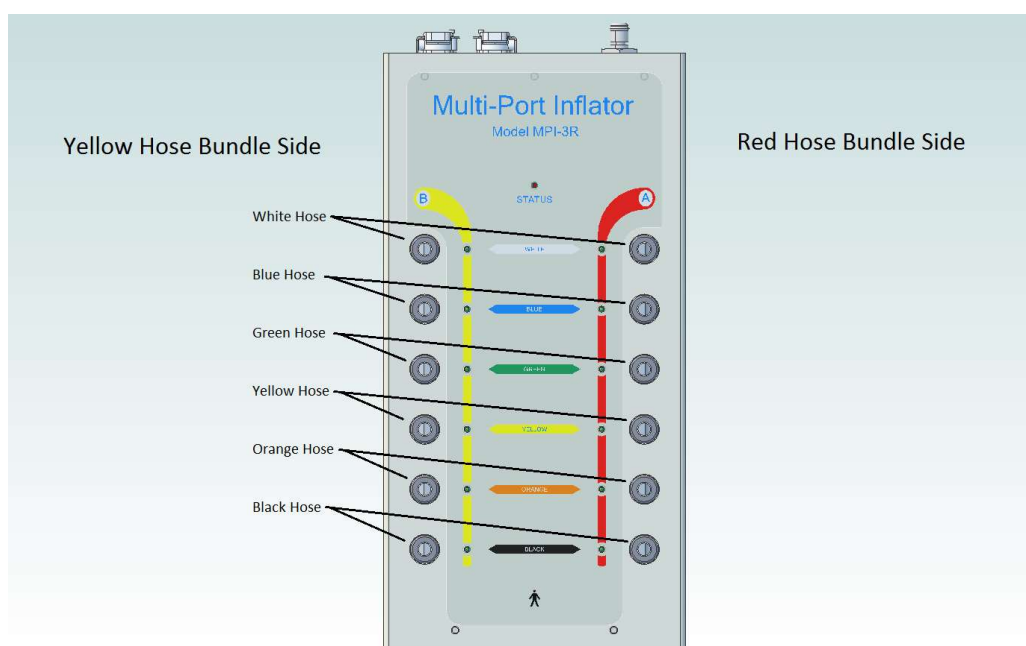
DESCRIPTION OF CONTROLS MULTI-PORT INFLATOR

PNEUMATIC OUTPUT

The MPI is designed to be used with the two Air Hose sets (or Hose Bundles) provided with the system, one “bundle” marked with a Red Band, the other with a Yellow Band. These generally (but do not always*) correspond to the patients Right side and Left side respectively.

Each Air Hose Bundle is comprised of 6 Air Hoses of different colors (see diagram below), all sheathed in Gray nylon webbing. The webbing is color coded at each end for identification with either a Red or a Yellow indicator band. In addition to the color bands, the individual hoses within each bundle are terminated with a blood pressure cuff air connector that is color coded Red or Yellow to help identify the correct connection at the patient.

The hose bundles are inserted into the MPI following the color coding provide on the MPI.



INSTALLING THE BUNDLED HOSE SETS

Before inserting the hose into the MPI (particularly if reinstalling previously used Bundled Hose Sets), visually inspect the hose end to make sure there are no cuts, scrapes or indentations on the outside of the hose end (the lower ¼” or so). If so, the hose end may be trimmed (approximately ¼”) to give a “fresh” surface so seal against. NOTE: The fittings used on the MPI seal on the OUTSIDE surface of the hose.

Insert the short colored ¼” diameter hose end into the circular gray hose connector ring which corresponds to that Hose and Hose Bundle. As downward pressure is applied to the hose, the installer should feel the hose “seat” approximately “1/4” after the hose makes initial contact. TIP: It is generally easiest to install the hoses starting with the shortest, black hose end, and then moving upward to the next longer hose end.

REMOVING THE HOSE BUNDLES

The Quick Release (QR) fittings used on the MPI have a collet lock with an internal O ring seal. These QR fittings, in combination with the tubing used at the MPI end of the bundles, will generally provide several years of trouble-free sealing. However, occasionally these hoses need to be removed....either for replacement or worn or damages hoses, or as part of routine maintenance. Again, in the event of a suspected seal failure, the hose end(s) may be trimmed to restore an effective seal.



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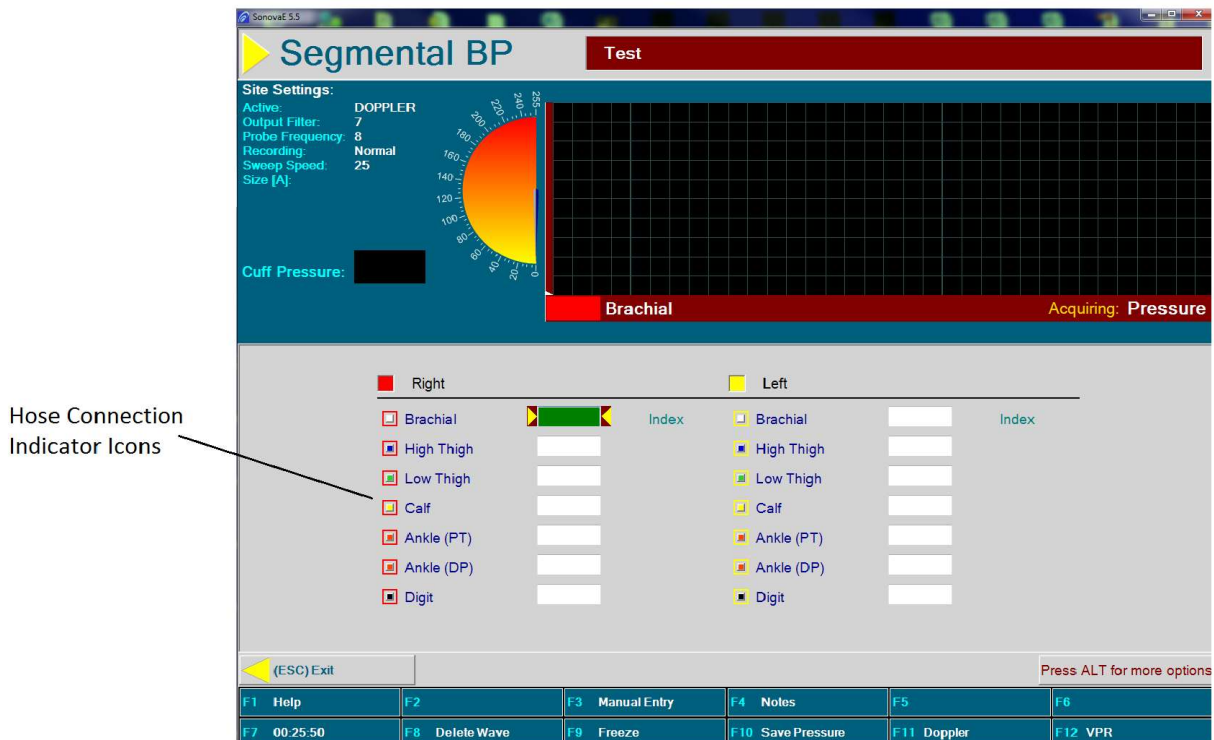


DESCRIPTION OF CONTROLS MULTI-PORT INFLATOR

To remove a hose, press downward on the circular gray ring surrounding the hose you are going to remove. The gray ring should depress (move downward) approximately .060" (~ 1/16"), disengaging the collet lock. While holding down the gray ring, pull upward on the hose to remove it. Repeat this step for each of the air hoses.

Connecting the MPI BUNDLED HOSES TO THE PATIENT

There are many different tests the Flo-Lab can perform which may require air connections to blood pressure cuffs. When a particular test requires the connection of the MPI to a patient cuff, connection icons are clearly displayed on the SonovaE test screen to assist the user in making the proper connection.



On each test screen which has the MPI configured to perform the cuff selection/switching, immediately to the left of each test site there will be an outer box indicating which hose bundle would connect to that limb/site (Red or Yellow), and inside of that box is a color coded square indicating which hose within that bundle should connect to that cuff.

In the close-up view in the example below, the patient's Right High Thigh cuff should be connected to the BLUE hose emerging from the Red Hose Bundle (This Blue hose will be terminated with a Red Air Connector Fitting). The Left Ankle cuff should be connected to the ORANGE hose emerging from the Yellow Bundle (this Orange hose will be terminated with a Yellow Air Connector Fitting).



DESCRIPTION OF CONTROLS

MULTI-PORT INFLATOR

Right			Left		
Brachial		Index	Brachial		Index
High Thigh			High Thigh		
Low Thigh			Low Thigh		
Calf			Calf		
Ankle (PT)			Ankle (PT)		
Ankle (DP)			Ankle (DP)		
Digit			Digit		

To further aid in patient connection, the individual hoses within each bundle have their lengths “staggered” so to that the next longer hose connect to the next lower cuff. This both simplifies/speeds connection of the air hoses to the patient cuffs, and allows the hoses to lie more orderly and unobtrusively once connected.

Though the Flo-Lab is provided with factory default settings pre-set (the Lower Arterial > Segmental Blood Pressure MPI defaults settings are shown above), the user may reconfigure SonovaE to use whichever works best in their situation. A listing of all of the factory default connections is provided at the end of this manual section.

BYPASSING THE MPI

The MPI is designed to eliminate moving hoses from cuff to cuff within a test (requiring disconnection and reconnection). There are times, however, when some users will find a single air hose more convenient for a particular part of the exam, or because of circumstances with the patient or testing environment. In this case the user may disconnect the main input hoses from the top of the MPI and run the hoses directly to the Patient. In most cases extension hoses will need to be attached as the hoses which connect the MPI to the main diagnostic module will likely be too short to reach. When this is done:

All Blood pressures are done by connecting the Red (A Channel) air hose to the selected Segmental/Digital cuff. This is true whether the cuff is on the patient’s Right Side or Left Side.

All PVR studies are performed by connecting the Red (A Channel) air hose to the selected Right side Segmental cuff, the Yellow (B Channel) air hose connected to the selected Left side Segmental Cuff.

When the MPI is bypassed, all system operations remain unchanged. The only difference is the user has to manually connect/disconnect the air hose, moving it from test site to test site as they progress through the test.

Using the Integral Bypass Valve

There are exams which are commonly ordered where very typically the user would prefer to perform the exam with a single air hose. Digit Blood Pressures is an example where the air hose (typically the black air hose within the Hose Bundle) needs to be moved from site to site whether the MPI is used for air distribution, or if the user has chosen to bypass the MPI.

To facilitate easily transitioning from the MPI Bundled Hose exams to Single Hose exams, the MPI is equipped with an Bypass Outlet port. When activated manually (or configured to automatically do so), the Red (A channel) Air Source is automatically rerouted out of the MPI, bypassing the switching manifold and effectively turning the Flo-Lab into a Single Hose Unit. The User may keep the bypass hose always connected, ready for rapid switching between Multiple Hose testing and Single Hose testing.

Some caveats:

List of Factory Defaults

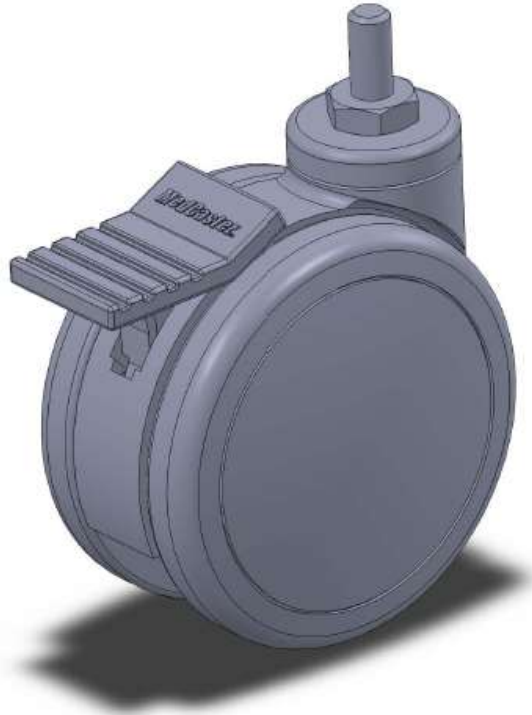




DESCRIPTION OF CONTROLS

FRONT AND BACK CASTERS

The 2100-SX2 is equipped with four antistatic swiveling casters for ease of maneuverability.



FRONT CASTERS

Pressing down on the lever on each of the front casters will activate the break to prevent the 2100-SX2 from rolling.

REAR CASTERS

Pressing down on the lever for each rear caster prevents the rear wheels from swiveling and locks them in a straight position. If the caster is turned when the lever is pressed, the caster will lock in the straight position as soon as the cart is rolled and the caster reaches a “straight” position.



THE SONOVAE SOFTWARE UTILIZES THE NETWORK FEATURE DICOM®.

To provide the safest and most secure operating environment for the Parks Flo-Lab it is recommended that the Flo-Lab not be connected to any computer network. This is the only sure way to avoid the possibility of malicious attacks, infections from computer viruses and worms and to ensure complete privacy of the data contained on the Flo-Lab computer system.

If the networking of the Flo-Lab with a local area network is required then Parks highly recommends the implementation of a firewall and anti-virus software with the latest updates and up-to-date virus definitions. Parks does not assume any responsibility for loss of data or system failures due to network security violations.

The Flo-Lab model 2100-SX2 runs on the Windows operating system. Parks encourages each facility to install and maintain the virus protection software used by your facility.

NOTE: To ensure that the SonovaE software runs optimally, do not run any virus scan or updates while in use on a patient.

* DICOM® is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

