

PHYSIOFLOW PF-05 Lab1

Service Manual

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Service Manual

PhysioFlow[®] Lab1[™]

1. General Information

About this manual

This manual contains all the required information for installation, use, maintenance, transport and storage operations for the PhysioFlow[®] Lab1[™] system. It has to be used with the user manual dedicated to the PhysioFlow Software V2.

It is designed for anyone involved in at least one activity described below.

Basic medical staff education associated to reading this manual is required to ensure a proper use of the medical device.

Basic technicians and maintenance staff education associated to reading this manual is required for any intervention on the medical device.

Contact

Manufacturer:

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Technical support

e-mail: support@physioflow.com

Symbols and Marks

Symbol	Signification
 WARNING:	Warning: no operator serviceable components inside. Do not remove covers. Refer servicing to qualified personnel.
	PhysioFlow power light
	Error light
	Connections linked to the patient are BF Type.
	« CE » mark followed by the notified organization's registration number. It ensures that the device meets the essential requirements of the European directive 93/42/CEE on medical devices.

2. Overall presentation



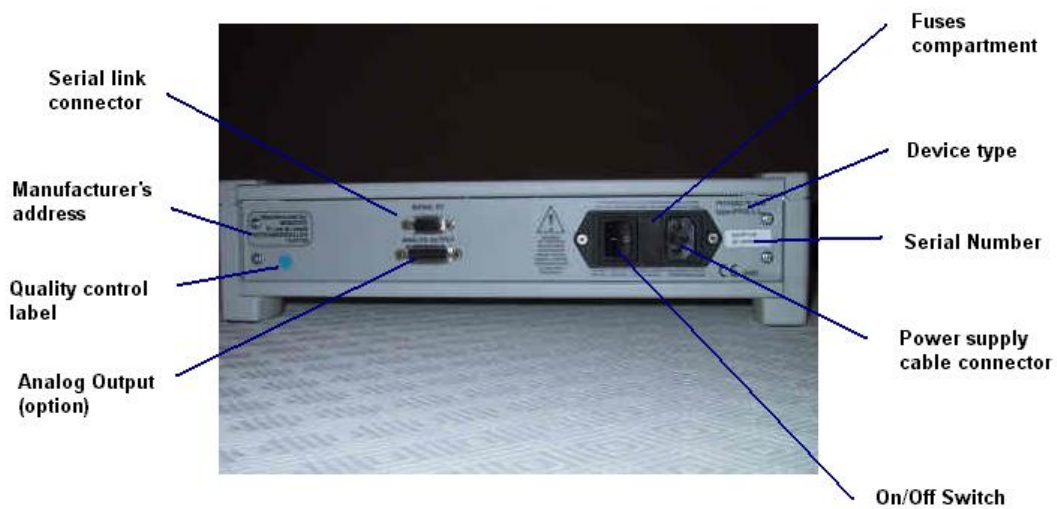
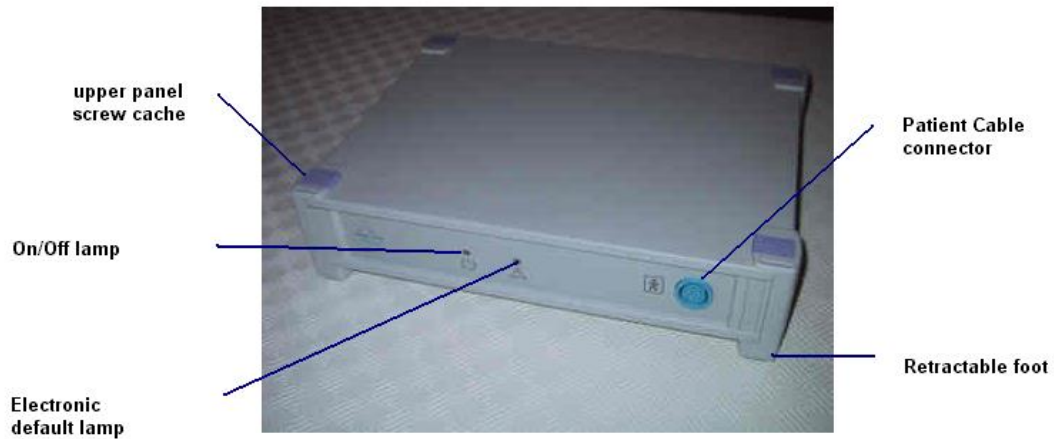
PhysioFlow is a non-invasive cardiac output monitor. It consists in an electronic device, connected to a PC compatible computer through a RS 232 C serial link. It is based on the principles of impedance cardiography.

The electronic unit performs impedance signal generation, reception of chest impedance modulation signal, analog and digital filtering, and digitisation of signal. And ECG signal is also recorded and digitised. It is used for time basis and heart rate computation.

A Windows based software performs signal sample collection, signal analysis, haemodynamic values computation, display of results, data storage and printouts.

3. Interfaces

Description of the electronic unit



Description of cables

A) Electrical RS-232 serial link cable (to be used with a laptop computer only)

Type zero modem, with SUB-D9 Male/Female connectors (fully EMI shielded)



B) Special optical RS-232 serial link cable (compulsory for use of PhysioFlow with a desktop computer)



C) Patient cable



Description of the inside of the unit



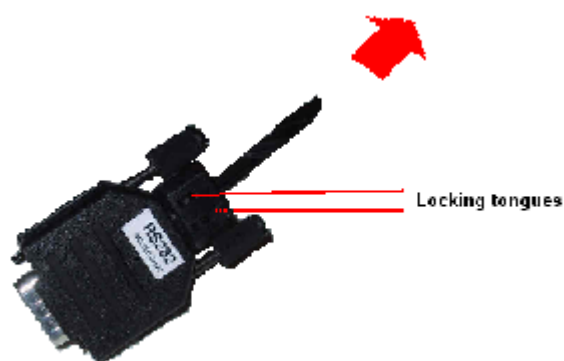
4. Instructions, Problems

Troubleshooting

The orange lamp is permanently on or flashes during measurement: please call your « after sales service » for instructions (customer support +33 3 72 82 50 00 or support@physioflow.com, or your local dealer)

The device does not switch on: please check fuses on back panel, and replace them if necessary. If problem remains, then call your « after sales service » for instructions (customer support +33 3 72 82 50 00 or support@physioflow.com, or your local dealer)

No ECG and no impedance signal are displayed: verify that the patient cable is connected on PhysioFlow and that the serial connection is OK. Replace electric RS 232 serial link cable if the problem remains. If you use an optical cable, check if the optical wire is properly plugged into the optical modules. You can as well unplug the wire on both sides, (by pulling the locking tongues on both sides of the module, and then pulling the wire out of the module). Then use a sharp cutter, and make a neat cut at the wire extremity. Plug the wire in the module again.



No ECG is displayed but other signals are visible: verify the quality of electrodes and their position. Electrodes must not be dry (use a bag that has been opened for less than one month).

ECG and Z signals are inverted: launch again the calibration or acquisition phase in progress.

Analog output pin connection and instructions

SUB-D 15 female connector on back panel.

Pin15 : Z
Pin 8 : Gnd
Pin13 : Stroke Volume
Pin 6 : Gnd
Pin11 : ECG
Pin 4 : Gnd
Pin9 : CO
Pin 2 : Gnd

The 4 outputs are -2.5V to +0.0V full scale / 10Kohms output impedance.

Please connect PhysioFlow to a medical system compliant with CE regulations or with your local medical regulations.

The Stroke Volume and Cardiac Output trends only operate when calibration phase is completed on the computer. The external data acquisition system has to be calibrated (adjustment of scales) to reproduce measurements displayed on the PhysioFlow Computer screen.

To perform this task, start a measurement on a volunteer who is very relaxed and stable. Please calibrate SV and CO measurement on your acquisition system in accordance with the readings you obtain on the PhysioFlow screen. Then make a change (for instance by retrieving the white electrode), and calibrate again your system in accordance with the new PhysioFlow readings obtained.



When using PhysioFlow Software 2.0.0 and later, only the Z (Pin15) and ECG (Pin11) outputs are active. In this case, it not possible yet to get neither CO on Pin9 nor SV on Pin13.
This feature is planned for a future software version. If you need it, please contact the technical support: support@physioflow.com.

5. Maintenance, Transport, Storage and Disposal

Service and maintenance

There is no operator or customer serviceable part, and no part has to be changed under normal tear and wear conditions.

If the system does not work properly, please refer to the troubleshooting section. If the problem remains, please contact your authorised dealer, or the customer support +33 3 72 82 50 00 or support@physioflow.com.

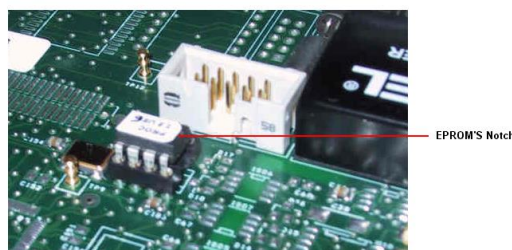
With special authorisation of the manufacturer or the dealer, the unit's embedded processor software can be upgraded. To perform this operation, it is necessary to replace the EPROM.

First stage is to open the enclosure. To do that, please slide the 4 caches on the upper side of the device, and unscrew.



Replacing the EPROM requires pliers, protected against static electricity. The EPROM must be retrieved very slowly and carefully from the support, by gripping the edges of the EPROM. Be careful, the new EPROM has to be put in place very carefully.

IT IS INDISPENSABLE THAT THE NEW EPROM IS POSITIONED THE SAME WAY THAN THE PREVIOUS ONE: THE NOTCH ON THE UPPER SURFACE MUST BE DIRECTED TOWARDS THE POWER SUPPLY (SAME DIRECTION AS THE PHYSIOFLOW LOGO ON THE FRONT PANEL AND OPPOSITE TO THE PATIENT CONNECTOR).



Storage and cleaning

Out of operation periods, the PhysioFlow unit must be stored at ambient temperature (between -40°C and +70°C, humidity included between 10% and 100%, and an atmospheric pressure included between 500 hPa and 1060 hPa).

The device and its accessories must be cleaned with a clean and dry or slightly wet cloth. **Don't plug the PhysioFlow on the electrical network during the cleaning operation.**

Appendix A: Legislation

Computer must comply with regulations concerning medical devices (Desktop computer, or laptop with leakage current under 0.1 mA). Please refer to the manufacturer information.

Please connect PhysioFlow to a CE marked device, compliant with medical norms.

LEGISLATION:

CE marking in accordance with EC directive 93/42/CEE concerning medical devices (class II A).
Device approved by the Japanese Ministry of Health.

Appendix B: Specifications

General	
Dimension	343 x 260 x 84 mm
Weight	4.0 Kg
Protection	Full EMI protection, (Metallic enclosure with special EMC shielding)
Power supply	100-240 VAC 50/60 Hz
Fuses	1A/250V only
Power input	50 VA
Galvanic insulation of patient, and optical coupling	Device of BF type
Electrodes	6 Ag/AgCl pregelled adhesive electrodes per examination Recommended : Agilent HP40493E
Connectors	
Back panel	Female SUB-D9 (serial link to PC) Switcher-filter-fuses module Schaffner
Front panel	Specific patient connector (6 leads + ground) Gilded contacts
Measurement current	Intensity of 3.6 mA peak to peak Sinus frequency : 75 KHz
Operating temperature	5°C - 55°C
Patient cable	6 leads, EMCD shielded Length 3.5 meters (ref. SP090) or 10 meters (ref SP090-10M) Gilded contacts
Specific RS232 serial link	Null modem type wiring (1,8 Meters) SUB-D9M/SUBD9F connectors Optical cable available, (for connection with a desktop computer).
Power supply cable	2P+T/CEE 22 (computer type) (3 meters)
Computer environment	
Minimal computer configuration	PC Pentium compatible Desktop or Laptop 200 MHz, 32Mb RAM, HD 50 Mb free, screen 800x600, 65536 colours Microsoft Windows 95 / 98 / Me / NT / 2000 operating system. 1 available serial link (RS 232)