



# USER MANUAL

Physio Flow PF-05 Lab1

Windows 95/98/Me/XP/2000 (32-bits) software version PF-1.05

## PREAMBLE :

Physio Flow is a noninvasive cardiac output measurement device who can be used in patients at rest or under exercise. If it is used on treadmill, please respect a moderated level of effort (<150 Watts).

## I) SOFTWARE INSTALL/UNINSTALL

### A. Software install.

Recommended minimal PC configuration :

**Pentium 400 MHz, 32 MB RAM, 50 MB free on Hard Disk, Windows 95, 98, or 2000.**

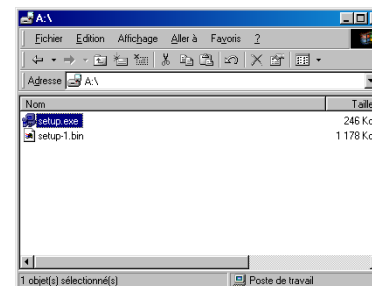
**Screen 800 x 600 pixels, ( 65 536 colours).**

**PC must be a laptop model, or a desktop with leakage current < 0.1 mA (Compatibility with medical safety regulations)**

Switch on your PC, wait until MS-Windows has finished to boot.

Insert the first diskette (labelled 'disk1') in the appropriate drive (A: , typically).

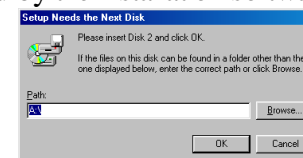
Double-click on 'My computer' then 'A: '.



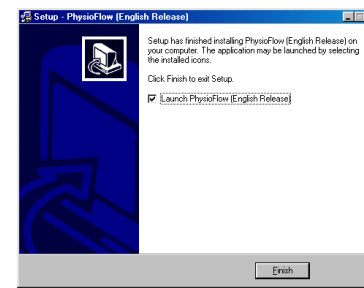
Display the content of this drive and double-click on the installation program 'setup.exe'.

Installation starts. Follow every step of the installation procedure, clicking on the "continue" button when appropriate.

Insert diskette 2 when asked by the installation software.



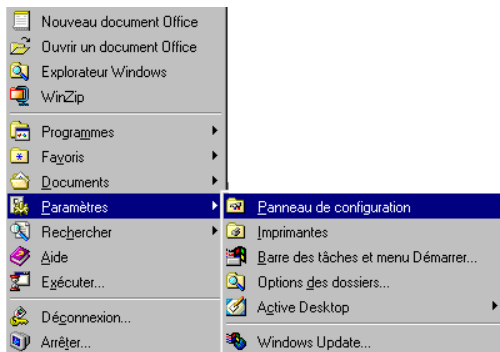
When the content of disk 2 is recorded, the following screen is displayed. If you want to launch Physio Flow immediately press 'launch Physio Flow(English release)', otherwise uncheck it. Whatever the case, press



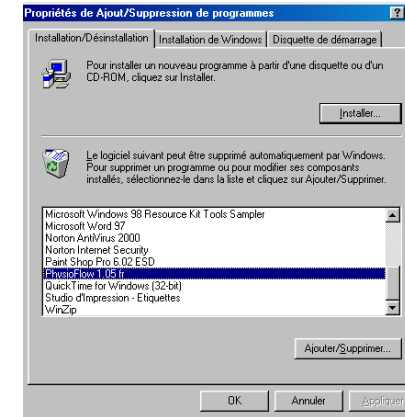
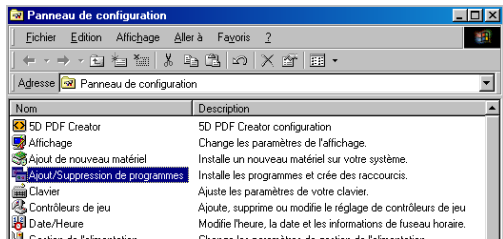
'Finish to' complete he procedure.

## B. Software uninstall.

To uninstall the software Physio Flow click on 'Start' ( tools bar on the screen's bottom). Select 'Parameter' and then 'Control Panel'.



Then double-click on 'Software install/uninstall'



Select Physio Flow among the software's list, press on 'Install/uninstall' on the bottom of the window and then click on OK.

## II) CONNECTIONS

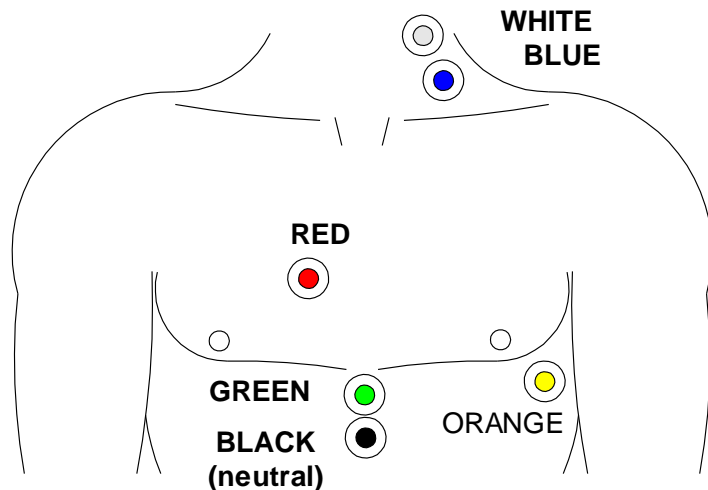
Connect Physio Flow to the electricity network (**CAUTION : A grounded plug is mandatory**).

Connect Physio Flow to the serial port of your computer, using the specific serial RS232 cable.

Connect patient cable on Physio Flow front panel.

Connect patient, using pre-gelled EKG electrodes (of good quality : Ag/AgCl are recommended).

The electrodes are placed on the thorax in the shown positions :



#### **ELECTRODES POSITION**

Two electrodes (red and orange) are used to monitor EKG in order to measure the heart rate :

All EKG derivations can be used, provided that EKG amplitude is correct

For instance :

**red (V1) - orange (V6)**

And four electrodes are used to monitor the impedance signal. recommended position is :

**white<sub>(up)</sub> - blue<sub>(down)</sub>** at the base of the neck  
(lateral triangle of the neck)

**green<sub>(up)</sub> - black<sub>(down)</sub>** at the xiphoid process.

For better operation, please shave patient's skin under electrodes, and clean skin (only if necessary).

Position of impedance electrodes is not critical provided that one pair is on neck basis, and one on thorax basis. If patient wears a pacemaker, put neck electrodes on the other side (right side of the neck if pacemaker is on the left side of the thorax).

To perform a bicycle exercise, please position V1 EKG electrode on the sternal manubrium, and avoid, if possible, positioning of upper impedance electrodes on the mastoidian muscle (neck basis), and lower electrodes over abdominal muscle. Fix patient cable wires on patient's skin with adhesive tape.

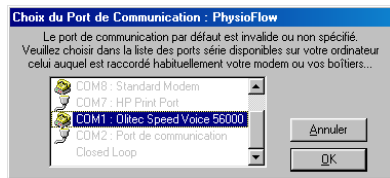
### **III) STARTING**

**Switch on Physio Flow (back side of Physio Flow).**

Make sure that *green* lamp is in function. *Orange* lamp (error) should only be switched on during a short period during start, and if major electronic default occurs (please contact us if it is the case).

When ready, start the Physio Flow program, either using the "Start", or double clicking on the corresponding icon, if you have created it.

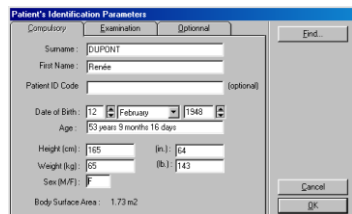
On first use of the program, you will prompted to choose the appropriate serial port on which Physio Flow is connected.



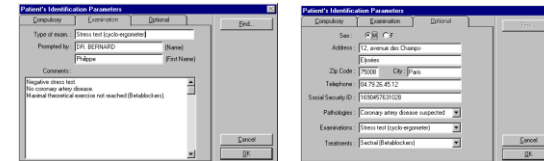
Acquisition screen appears. Click on the “new” control button (upper left).

Introduce patient identification. Name, First Name, and other parameters on the first page are mandatory. Then go to “Clinical Parameters” and introduce patient Height and Weight (mandatory).

You can also click on “Find” to select a patient you have already measured, (modifications of parameters, for instance weight, are allowed).



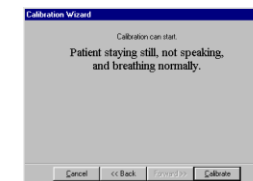
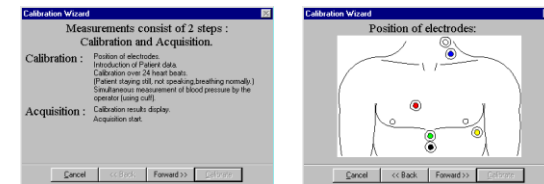
You can fill fields in ‘Exam’ and ‘Options’. You can go from a field to another field with TAB key.



Click on OK when finished.

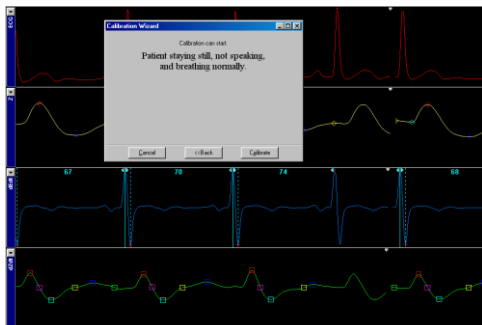
#### IV) CALIBRATION

Please read carefully calibration instructions on Calibration Wizard screen. Calibration is particularly important : reliability and reproducibility depend on it. It is performed on 30 heart beats, with best possible signal stability.



It is necessary to proceed to simultaneous blood pressure measurement, using manual or automatic blood pressure monitor, in order to obtain blood pressure reference values (they are used as a reference for blood pressure profile calculation during exercise).

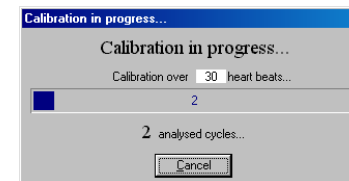
EKG and impedancemetric signals are displayed on the screen from the start of this phase. Before proceeding to calibration, make sure that they are reproducible, stable, and without artifacts or interference.



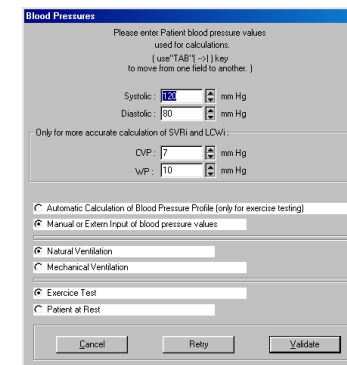
**Important :** the operator should check that heart rate results appear well beat by beat on the  $dE/dt$  signal (light blue digits, dark blue signal). Similarly, he will verify that characteristic points of the  $dZ/dt$  (green) signal are correctly detected (presence of red and yellow squares on the signal is necessary). Yellow square must not appear at the end of the heart cycle.

If the signal treatment does not operate in good conditions, the operator should try another derivation for the EKG (red electrode on the right shoulder and orange electrode on the left hip, for example), and for the impedance (move horizontally the pair of electrodes situated at the base of the thorax (green and black)).

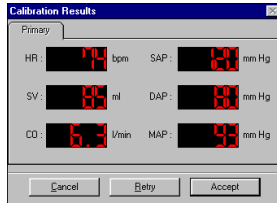
If signal is satisfactory, then click on “ Calibration ” to proceed.



Wait until calibration is finished (30 heartbeats), and introduce systolic and diastolic blood pressure when asked. It is possible to modify default CVP and WP parameters. If you check the ‘Manual Input of Blood Pressure’ option, you will be allowed to enter new blood pressure values during the monitoring, using keyboard. The default “Automatic calculation” adjusts parameters automatically in accordance with the evolution of the impedance signal waveform.



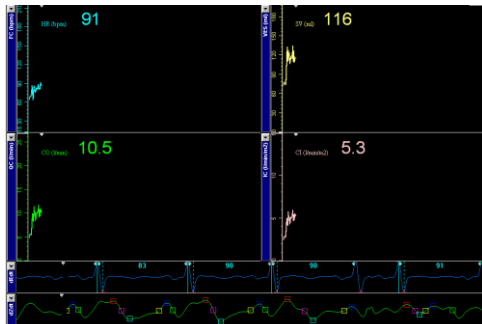
You may verify Calibration results, and click on “ accept ” if they are correct. Monitoring starts.



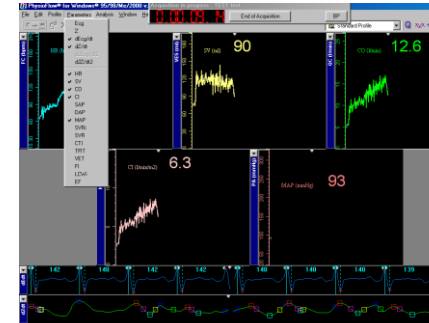
If the calibration looks wrong (bad quality of signal, aberrant values), you can start again the calibration (« Retry »).

## V) MONITORING

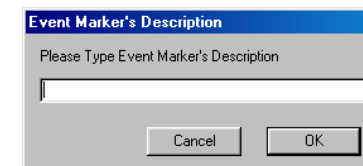
Monitoring screen appears (HR = Heart Rate, SV = Stroke Volume, CO = Cardiac Output/Index (cardiac output divided by body surface area), SAP, MAP, DAP (systolic/mean/diastolic arterial blood pressure)).



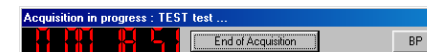
By using the “Parameters” menu on Tools bar, you can select or deselect parameters you want to display on screen.



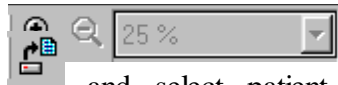
During the monitoring, you have the possibility of mark some events. When you wish to indicate an event, press SPACEBAR. A window appears and asks you for the text. Click OK or press “enter” to validate, then this event appear as a vertical line on the screen.



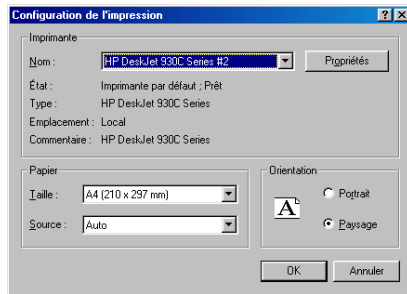
Click on “End of acquisition” if you want to stop acquisition. On this same window, a “BP” button appear if you have selected the manual input of blood pressure option. This button allows to enter blood pressure parameters manually during measurements.



## VI) REVIEWING ACQUISITION



Click on the “open” button (on Tool bar), and select patient and measurement you want to display. Measurements are sort by date, the last is on the top. You can print a printed report using the “print” button.



A window appears and asks you how many exemplary you want print and the act of the pages that you want print.

## VII) PRINT PREVIEW



You can select ‘Print preview’ in the ‘File’ menu. This option allows to visualise pages as they will be printed and choice the page that you will print.



Allow to view the full page or in real dimensions.

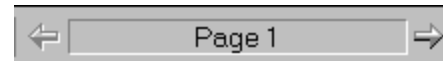
Allow to choose zoom for best viewing of the page. It does not modify the dimensions of the printout.



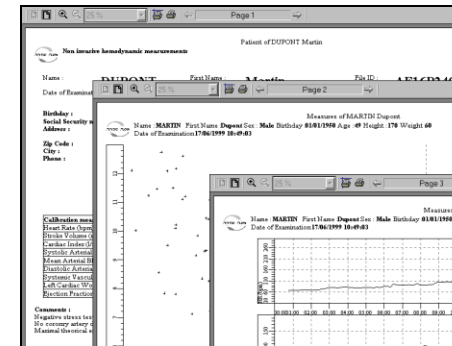
Allow to modify margins and page that you want to print. You can also select signals and modify header and footer of the page.



Allow to print as the print button of the tool bar of the software.



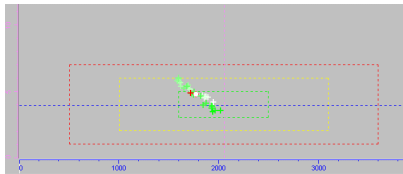
Allow to view the pages one by one (for choosing those you want to print).



## VIII) OTHER ANALYSIS WINDOWS

◆ Hemodynamic cross :

Click on 'Hemodynamic cross' of the 'Analysis' menu for displaying results in hemodynamic cross (Left Cardiac Work Index plotted against Systemic Vascular Resistance Index).



(Actual color is black instead of grey).

◆ Values board :

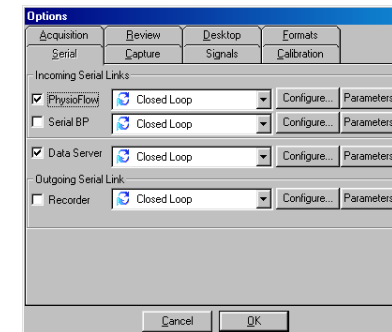
Click on 'Measurements' of the 'Analysis' menu for displaying the numeric values listed according to elapsed time.

Main Measurements		Other Measurements											
Elapsed Time	Time	HR	SV	CO	SAP	DAP	MAP	SVRI	LCWi	CI	SVR	Q	Marks
00:00:09	10:58:25	87	73	4.9	120	80	93	3026	3.32	2.5	1525		
00:00:17	10:58:35	71	78	5.6	120	80	93	2654	3.78	2.8	1338		
00:00:26	10:58:44	72	79	5.6	120	80	93	2631	3.81	2.8	1326		
00:00:34	10:58:52	74	77	5.7	120	80	93	2800	3.86	2.9	1311		CDM Port Problem
00:00:43	10:59:01	72	77	5.5	120	80	93	2671	3.76	2.8	1346		CDM Port Problem
00:00:52	10:59:10	77	75	5.7	120	80	93	2593	3.87	2.9	1307		
00:00:59	10:59:17	80	82	6.2	120	80	93	1797	5.58	4.2	906		CDM Port Problem
00:01:06	10:59:24	84	118	9.9	120	80	93	1492	6.72	5.0	752		
00:01:15	10:59:33	67	133	8.9	120	80	93	1658	6.05	4.5	836		
00:01:23	10:59:41	75	111	8.3	120	80	93	1775	5.65	4.2	894		
00:01:30	10:59:48	89	128	11.4	120	80	93	1300	7.72	5.7	665		
00:01:37	10:59:55	86	113	9.7	120	80	93	1528	6.57	4.9	770		
00:01:44	11:00:02	82	124	10.1	120	80	93	1462	6.86	5.1	737		CDM Port Problem
00:01:52	11:00:10	80	108	8.6	120	80	93	1722	5.83	4.3	868		
00:01:59	11:00:17	86	113	9.6	120	80	93	1536	6.53	4.9	774		
00:02:06	11:00:24	86	118	10.1	120	80	93	1463	6.86	5.1	737		
00:02:13	11:00:31	85	119	10.1	120	80	93	1471	6.82	5.1	741		
00:02:20	11:00:38	87	120	10.4	120	80	93	1426	7.04	5.2	719		
00:02:27	11:00:45	91	115	10.5	120	80	93	1412	7.11	5.3	711		CDM Port Problem
00:02:34	11:00:52	87	135	11.8	120	80	93	1257	7.98	5.9	633		
00:02:42	11:01:00	84	111	9.4	120	80	93	1584	6.33	4.7	798		
00:02:49	11:01:07	85	127	10.8	120	80	93	1375	7.30	5.4	693		
00:02:56	11:01:14	88	109	9.6	120	80	93	1545	6.50	4.8	778		
00:03:03	11:01:21	95	116	11.0	120	80	93	1346	7.46	5.5	678		
00:03:09	11:01:27	91	116	10.5	120	80	93	1405	7.14	5.3	708		
00:03:17	11:01:35	88	127	11.2	120	80	93	1319	7.61	5.7	665		
00:03:23	11:01:41	90	112	10.0	120	80	93	1475	6.80	5.1	743		CDM Port Problem
00:03:30	11:01:48	88	118	10.4	120	80	93	1424	7.05	5.2	717		
00:03:37	11:01:55	90	128	11.4	120	80	93	1296	7.74	5.8	653		

## IX) ADVANCED FEATURES

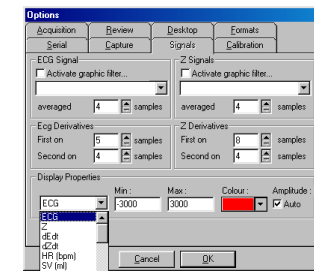


By clicking on “preferences” (Tool bar), you can modify some settings :



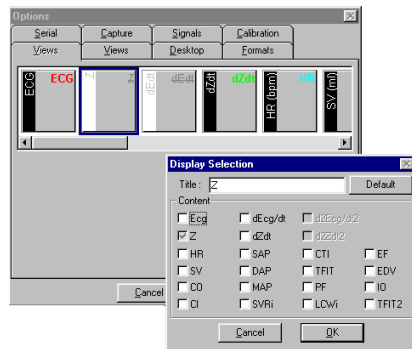
Serial : you can select COM2 as incoming serial link if COM1 is already used by another system.

Signals : you can modify display properties (for instance colours associated with parameters).





Views: you can decide to modify monitoring screens content, (for instance displaying two parameters on same screen). Select your parameter using left mouse button, then use right mouse button to modify screen and insert the chosen parameter.



Please do not try to modify other settings without prior notice to our after sale service.

## X) PROFILES

Every user of the Physio Flow can define some functions according to his work preferences, so that the Physio Flow is flexible and can be used by many persons.

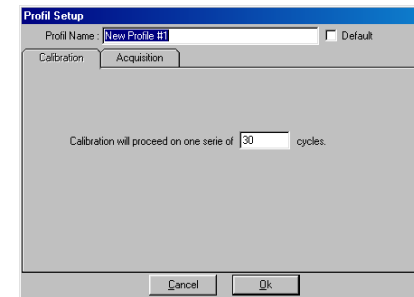
For selecting a profile, you must click on the corresponding icon :



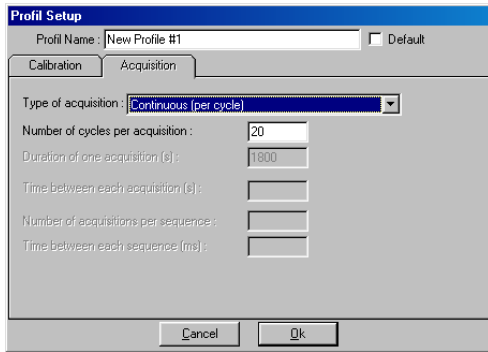
For creating or modify a profile, you must click on 'Profil' and after on 'Add/Delete or Modify'.

A parameters window with two thumbnail appears :

The first, 'Calibration', allows to select automatic calibration (by default) and choose the number of cycles during the calibration phase (2 x 12 by default).



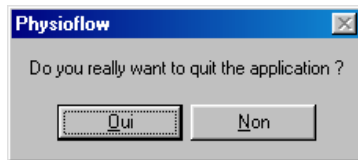
The second, 'Acquisition', allows to choose the acquisition mode (continue, sequential, ...), the number of cycles for each measurement (12 by default), number of acquisitions and sequence (in seconds).



## XI) EXIT



You can exit Physio Flow software by clicking on the door (upper right side, on Tool bar).



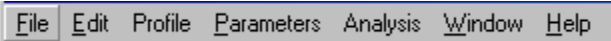
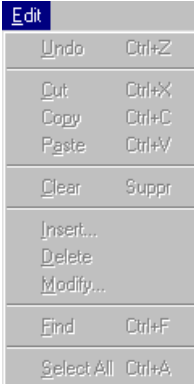
*I've added this window.*

Thank you for using Physio Flow.

## XII) STORAGE, MAINTENANCE

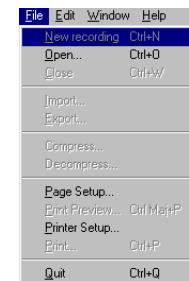
Out of operation periods, the Physio Flow must be stored at a ambient temperature (between -40°C and +70°C, humidity included between 10% and 100%, including condensation, and an atmospheric pressure included between 500 hPa and 1060 hPa).

The device and its accessories must be cleaned with a clean and dry or slightly wet cloth . Don't plug the Physio Flow on the mains the during the cleaning.



## APPENDIX A : SUMMARY TABLE OF MENUS

### 'File' menu :



New recording : allows to begin a new acquisition.

Open : allows to load an old acquisition.

Close : close actual acquisition.

Import : *not available in this software version.*

Export : save values as .txt or .csv format.

Compress : *not available in this software version.*

Decompress : *not available in this software version.*

Page setup : allows to choose margins, header, footer of pages.

Print preview : displays sheets how they will be printed.

Printer setup : displays the configuration printer board.

Print : prints the report.

Quit : exit of the software Physio Flow.

### **‘Edit’ menu :**

Undo : *not available in this software version.*

Cut : *not available in this software version.*

Copy : *not available in this software version.*

Paste : *not available in this software version.*

Clear : *not available in this software version.*

Insert : *not available in this software version.*

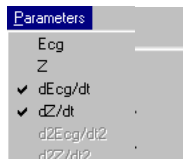
Delete : *not available in this software version.*

Modify : *not available in this software version.*

Find : *not available in this software version.*

Select all : *not available in this software version.*

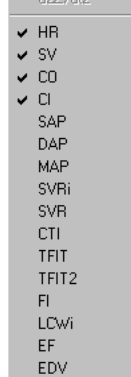
### **‘Profiles’ menu :**



Add : allow to add an user profile.

Delete : allow to delete an user profile.

Modify : allow to modify an user profile.



### **‘Parameters’ menu :**

#### Visible signals :

ECG : electrocardiogram signal.

Z : impedance signal.

dECG/dt : electrocardiogram signal first derivative.

dZ/dt : impedance signal first derivative.

d<sup>2</sup>ECG/dt<sup>2</sup> : electrocardiogram signal second derivative.

d<sup>2</sup>Z/dt<sup>2</sup> : impedance signal second derivative.

#### Visible data :

HR : heart rate (bpm)

SV : systolic volume (ml)

CO : cardiac output (l/min.)

CI : cardiac index (l/min./m<sup>2</sup>)

SAP : systolic arterial pressure (mmHg)

DAP : diastolic arterial pressure (mmHg)

MAP : mean arterial pressure (mmHg)

SVRi : systemic vascular resistance index(d.s.cm<sup>5</sup>/m<sup>2</sup>)

SVR : systemic vascular resistance

CTI : contractility index (no unit)

TFIT, TIFT2 : thoracic flow inversion time (related to the ventricular ejection time) (ms).

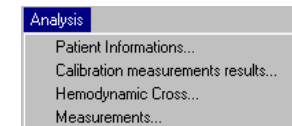
FI : filling index

LCWi : left cardiac work index (kg.m/m<sup>2</sup>)

EF : ejection fraction (est.) (%)

EDV : end diastolic volume (est.) (ml)

### **‘Analysis’ menu :**



Patient information : Display patient information and allow

to, modify this.

Calibration measurements results : Display data measured during the calibration phase.

Hemodynamic cross : Display the hemodynamic cross graphic.

Measurements : Display the table of figures representing measured parameters.

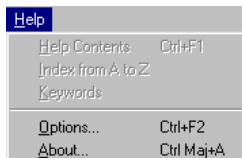
**‘Window’ menu :**



Tools bar : view/mask the tools bar.

Messages bar : view/mask the message bar.

**‘Help’ menu :**



Help contents : Open the help file.

Index from A to Z : give a list of all help chapters.

Keywords : search by words in the help.

Options : allows to configure the software.

About : software version.



## APPENDIX B : Tools bar

create new acquisition.

open an recorded acquisition.

close a displayed measurement



save the acquisition.



import an acquisition.

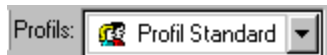
export in text or csv format

print rapport.

open the Physio Flow configuration board.

launch the index help

launch the contextual help.



allow to choose a profile.



profile parameters.



quit the Physio Flow software.

## APPENDIX C : Troubleshooting



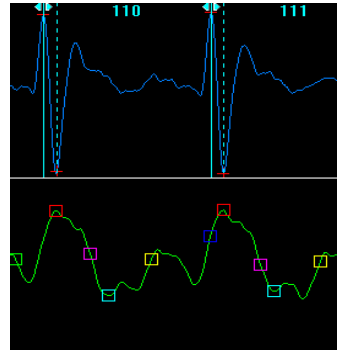
- **The *green* lamp on the unit is not lighting** : verify that the Physio Flow is connected to the mains and switched on.



- **The *orange* lamp is on** : please, call your « after sales service » (customer support 00 33 1 43 87 88 13 or [manatec@easynet.fr](mailto:manatec@easynet.fr)) or your local dealer.



- **No ECG and no impedance signal are displayed** : verify that the patient cable is connected on Physio Flow and that the serial connection is OK. Verify configuration of serial port by clicking



on, and try to select another communication port (COM2 instead of COM1, for instance)

- **No ECG is displayed but others signals are visible** : verify the electrodes quality and their position.

- **There is conflict between communication ports :** If you have an infrared port, disconnect it (by clicking on the icon infrared in the Windows task bar). Verify that nothing is connected on the same communication port.
- **ECG and Z signals are inverted :** launch again the calibration or acquisition phase in progress.
- **The software is completely blocked :** Press simultaneously Ctrl + Alt + Del two times to restart computer.
- **No printouts can be obtained :** Please check if a printer is connected, and if the suitable printer driver is installed. If you have a series 900 HP Deskjet printer, please use the HP895Cxi driver (downloads available on [www.hp.com](http://www.hp.com)).
- **Unclear signal quality is obtained :** Please check signal quality using following reference :

**ACCEPTABLE SIGNAL**

QRS should be properly detected (light blue lines), and heart rate displayed every beat.  
 Colour squares on the dZ/dt signal (red to yellow) should draw a curve oriented downwards (during systolic phase)

EXAMPLE I

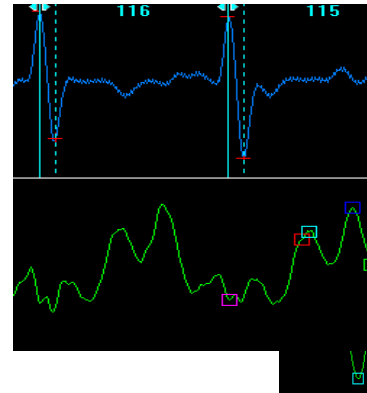
EXAMPLE II

EXAMPLE III

**POOR SIGNAL**

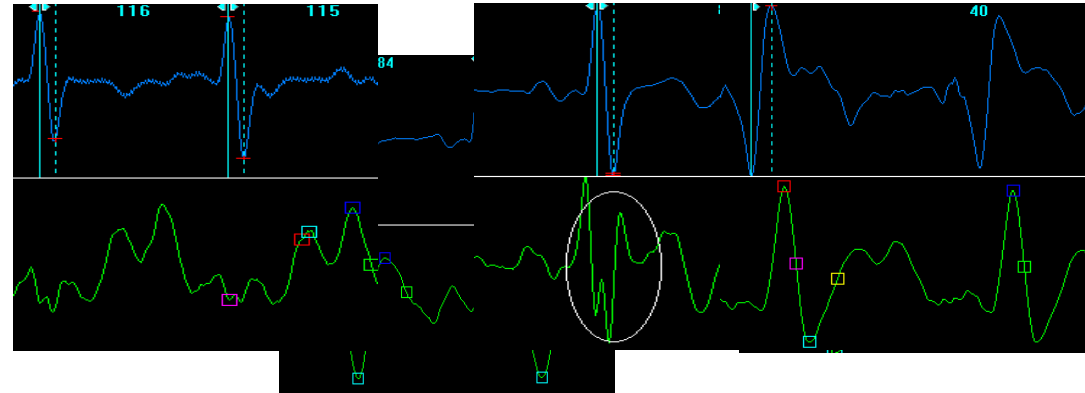
EXAMPLE I :

No systolic curve during dZ/dt squares are not regularly plotted



EXAMPLE II :

Artefact on dZ/dt curve, occurring during QRS



SOLUTION I :

Clean and shave the skin ,  
 replace impedance electrodes,  
 Reposition impedance electrodes  
 (on the same horizontal level)

SOLUTION II :

Clean and shave the skin,  
 replace impedance electrodes,  
 Reposition impedance electrodes  
 (on the same horizontal level).

EXAMPLE III :

EXAMPLE IV:

Electrical interference Colour  
Static electricity on ECG

A majority of QRS are not properly detected  
And heart rate is wrong  
Often occurs in case of bundle branch block  
or pacemaker patients (QRS large and of low  
dynamic)

SOLUTION III :

If allowed, turn off the  
source of static electricity.

SOLUTION IV:

Increase ECG sensitivity  
(see Signal Setup on the tools bar)



Windows 95 / 98 Software  
Power : 100-240 VAC  
Fuses 1A/250V only  
Measurement current : 1.9 mA RM, 75 KHz  
Full galvanic isolation of patient  
Full EMI protection

### **LEGISLATION :**

Physio Flow complies with : EN60601-1  
Following norms EN60601-1-1  
EN60601-1-2

Manufactured in France in accordance with ISO9002 norms.  
CE marking in accordance with EC directive 93/42/CEE concerning medical devices  
(class II A).

## **APPENDIX D : SPECIFICATIONS**

### **Specifications**

Dimension : 343 x 260 x 84 mm

Weight : 4.0 Kg

Minimal computer configuration : PC Pentium compatible 100 MHz, 8Mb RAM, HD  
50 Mb free, screen 800x600, 65536 colours

## VERY IMPORTANT :



WARNING  
NO OPERATOR  
SERVICEABLE  
COMPONENTS  
INSIDE DO NOT  
REMOVE COVERS.  
REFER SERVICING  
TO QUALIFIED  
PERSONNEL.

- **Physio Flow must be used and stored in a clean and dry environment. Avoid liquid projections on case. Do not cover ventilation openings on case.**

- **There are no operator serviceable parts inside the case. Do not remove covers. Refer to qualified personnel only.**



- **Use only Physio Flow specific spare parts.**



- **Manatec Biomedical is not responsible for misuse of its products, nor installation of software on a computer with wrong setup or configuration, or a computer infected with viruses.**



- **Manatec biomedical is not responsible if Physio Flow is connected to a computer that does not comply with medical safety regulations. PC must be a laptop model, or a desktop with leakage current < 0.1 mA (Compatibility with medical safety regulations). Manatec Biomedical is not responsible if PC is modified (installation of electronic boards).**

CE<sub>0459</sub>

## ACRONYMS DEFINITION :

Warning, no operator serviceable components inside. Do not remove covers. Refer servicing to qualify personnel.

Physio Flow power light.

Error light.

Patient cable connector.

CE marking of the system.





*PHYSIO FLOW PF-05 Lab1*

# *Operating Instructions*

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*November 2001*

***manatec biomedical***

*limited capital : FF. 200.000*

*R.M. : 402 547 574 RM 57*

*SIRET : 402 547 574 000 10*

*APE : 332 B*

*21, rue du Stade 57730 PETIT-EBERSVILLER*

***Commercial offices:***

*44, rue de Laborde*

***75008 PARIS-France***

*E-mail : manatec@easynet.fr*

*tél : (+ 33) 1 43 87 88 13*

*fax : (+ 33) 1 43 87 70 83*

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