PHYSIOFLOW ENDURO

Service Manual

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Service Manual

PhysioFlow® Enduro

1. General Information

About this manual

This manual contains all the required information for installation, use, maintenance, transport and storage operations for the PhysioFlow Enduro 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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E-mail: support@physioflow.com

For any additional information about PhysioFlow products, please contact our services:

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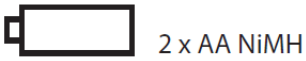
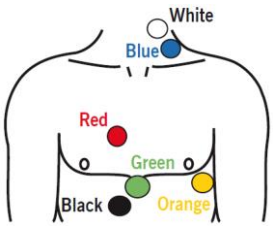
Technical support
e-mail: support@physioflow.com

Symbols and Marks

Symbol	Signification
	Refer to instruction manual for the device and the software. Instruction manuals must be read.
	Connections linked to the patient are B Type.
	Device powered by 2 x AA NiMH batteries
CE 0459	« 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.
	The Enduro product is classified according to the WEEE directive (2002/96/EC) as reporting to processing of electrical and electronic equipment. Therefore, it can't be treated as household waste. Its recycling must be done in specialized recycling centers. (cf. *"Disposal"* section)
	The device includes a radio frequency transmitter
	Placement of the electrodes.

	In the manual this symbol indicates that one or several conditions could damage the equipment itself and/or impact patient's and/or user's and/or environment's safety.
	Important information to consider for an efficient and optimized use of the system.
IPX0	Solid particle protection (X): Degrees of protection not specified. Liquid ingress protection (0): Not protected. (This symbol doesn't appear on the product label).
	Symbol meaning « MANUFACTURER » followed by: Manatec Biomedical 21, Rue du stade, Petit Ebersviller 57730 Folschviller - France Tel: +33 (0)3 72 82 50 00 Fax: +33 (0)1 30 74 46 48

2. Overall presentation

PhysioFlow Enduro is a portable and standalone noninvasive cardiac output monitor. It consists in an electronic device, connected to a PC compatible computer through a wireless Bluetooth 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 digitization of signal. And ECG signal is also recorded and digitized. It is used for time basis and heart rate computation.

A Windows based software performs signal sample collection, signal analysis, hemodynamic values computation (When not in standalone mode), display of results, data storage and printouts.

3. Device Installation: The Enduro System

Minimum configuration requirements / Accessories

To work properly the Enduro requires a computer with at least one available USB port and the following accessories:

- USB SENA UD-100 Bluetooth Antenna (No driver required, automatically detected and installed by Windows operating system)
- Batteries. Two possible options:
  - ✓ Rechargeable batteries (fresh and fully charged): Energizer 2450mAh or Sanyo eneloop XX 2450mAh (HR-3UWXA/B).
  - ✓ Not rechargeable batteries (freshly opened): Energizer Ultimate Lithium AA
- USB cable (1.8m). USB interface could be used for memory download operation (USB interface can't be used for communication during real time monitoring).

PC environment must have at least the following characteristics:

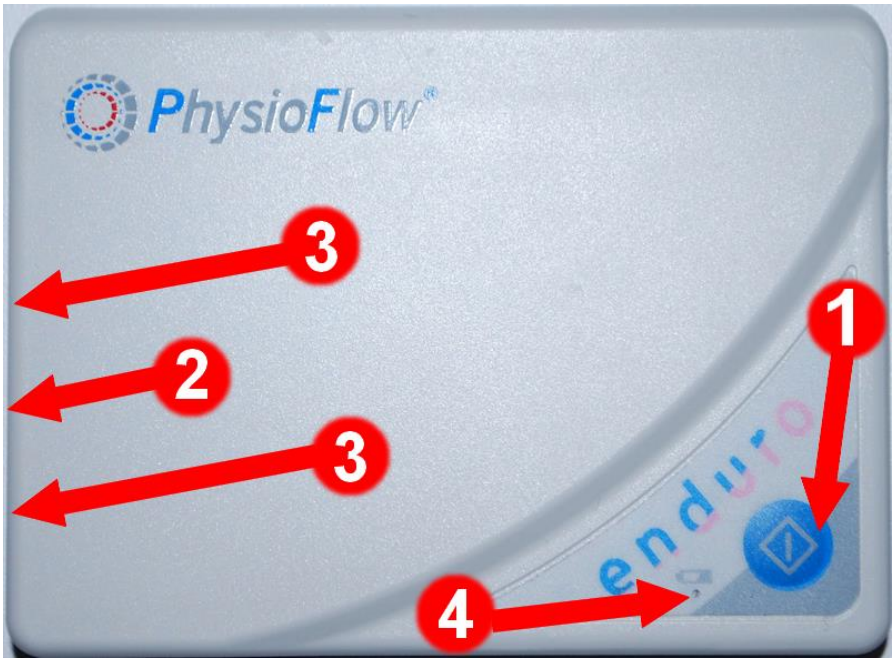
- Operating system: Microsoft Windows XP, Vista, Seven
- 2GHz dual core X86 Processor
- 4GB MB RAM
- 250MB Free hard disk space for installation
- Minimal size of screen advised : 15 inch/ 15 '' chips XGA (1024 x 768)

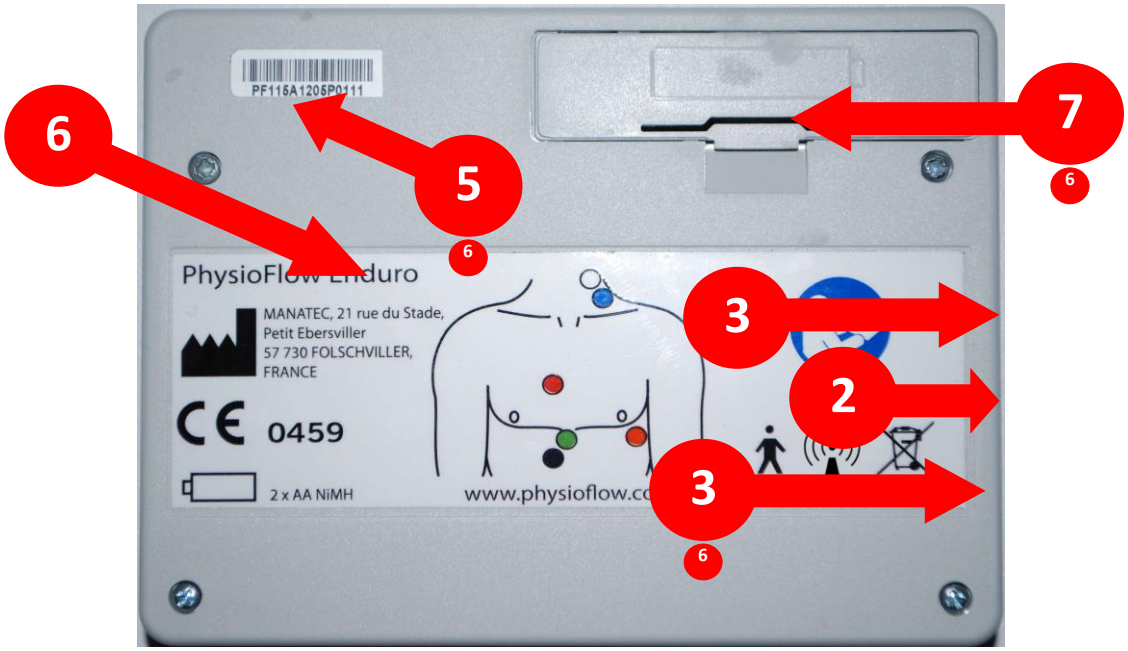
	*The computer used, as a minimum requirement, must comply with the relevant standard for information-processing equipment (CEI 60950-1), and more specifically, the medical standards if it is used/installed within the patient's environment. (*cf. *"Definition"* section*)*

	*10GB free space on the hard drive is recommended to store monitoring data.*
	Manatec does not support other accessories than the ones listed above.
	Batteries performances are decreasing over time due to aging and accumulation of charge/discharge cycles. Even if batteries are considered as fully charged following problems could occur: ▪ When Enduro is switched on or monitoring is launched, the device is tested: *the boot sequence fails (LED indicator turns to red)* ▪ *Enduro / PC Bluetooth connection problems* ▪ *Measurement session does not last as long as expected* ⇨ *In this case it is recommended to recycle old batteries and use new ones.* *The batteries should be removed from the device when you do not intend to use it. Acid leaks may damage the unit irreparably.*

Interfaces

The Enduro has a limited number of interfaces that makes the device intuitive and simple to use.





1. Push button reserved for future use
2. USB mini connector: for memory download purpose only
3. Patient cable interface with mechanical mistake proof system
4. LED indicator: It must be constant green and flashing when an acquisition is running. When switched on, the device is tested, the indicator is orange. At the end of the test, it changes to

green if all the checks are correct. If not, the indicator changes to red (batteries fail to deliver the required power and must be replaced). The operator has to change batteries.

5. Device serial number
6. Sticker with regulatory information
7. Batteries compartment. The battery compartment cover gives direction regarding the polarity for correct insertion.

	*Do not open the enclosure.*
	For memory download purpose, operator only uses the provided USB cable. The USB connector should only be used through a standard USB port indicated by the following symbol :  *Do not force the USB cable with another type of port.*

	*When the device is used, the operator must pay attention to maintain the Enduro within the Bluetooth signal range: Up to 50 meters in open spaces using the recommended Bluetooth antenna.* *As far as it is possible in order to prevent any risk of data flow interruption, the operator will work in an open space configuration.*

Installation

The hardware installation process is limited to Enduro communication interfaces:

- Wireless Bluetooth connection trough Sena UD100 Bluetooth antenna.
- USB interface when the Enduro is plugged to the PC.

In both cases no specific driver is needed. Windows operating system automatically installs and configures Sena UD-100 and Enduro USB interfaces.

Once the drivers are installed communication link is automatically configured when PhysioFlow software is launched (Please refer to PhysioFlow Software user manual for more information).

If there are any problems or questions with the installation of the device, please contact technical support: support@physioflow.com.

4. Maintenance, Transport, Storage and Disposal

Maintenance

Generalities

The Enduro does not need any calibration or service operation during normal use. Final user and technicians are not qualified to service the system.

The device and its accessories must be cleaned with a clean and dry cloth or lightly moistened with a mixture of water and neutral soap. Do not connect the PhysioFlow to the computer while cleaning. If the system has been contaminated by a patient's blood or body fluids, clean and disinfect in the same way as for the patient cables.

Life cycle of the product and its main accessories:

Patient cable	2 years from the date of first use
Enduro system	7 years from the date of first use
Electrodes	Single use only. Expiration date is printed on the pouch

	*Any maintenance and service operations must only be carried out by Manatec Biomedical.* *The enclosure must not be opened by the user (operator and technician).* *No modification of the equipment is allowed.*

Identification of the embedded software version

The embedded software versions are set by the PhysioFlow Software installed on Windows. For more information about embedded software version please contact Manatec Biomedical technical service and give PhysioFlow software V2 version number (refer to the PhysioFlow user manual section "**Erreur ! Source du renvoi introuvable.**" for more information). (support@physioflow.com).

Storage and transport

When it is not used, the PhysioFlow device must be stored at an ambient temperature between -18°C and +38°C, a relative humidity between 10 % and 70 %, and an atmospheric pressure between 500 hPa and 1060 hPa.

When the PhsyioFlow is not used, please pack it in the foam padded cardboard box that the device was delivered in.

Disposal

PhysioFlow Enduro device: Do not throw away. Some components can be recycled according to European Directive 2002/96/EC (WEEE). The device must be sent to Manatec Biomedical Company or given to recycling specialized services (contact local authorities services for further information about this matter).

Outside the European Union: Send the device back to Manatec Biomedical Company or comply with the laws applicable in the country where the device was in use.

Return address: Manatec Biomedical
10, bis rue Jacob Courant
78300 Poissy
France

Computer: Do not throw away. Please refer to the manufacturer's instructions.

Electrodes: They are for single use only. Do not use for more than 24 hours on the patient. Once the measurement is completed, please throw away.

Appendix A : Accessories

For any order or request concerning the accessories, please contact us at: sales@physioflow.com

Reference	Designation
ENDURO_1001	Patient cable
ENDURO _2001	PF50 PhysioFlow Electrodes
ENDURO _2002	Abrasive gel Nuprep
ENDURO _3001	Pouch
ENDURO _4001	1.8m USB cable
ENDURO _4002	Bluetooth antenna SENA UD100
ENDURO _4003	AA Rechargeable batteries (x4) & Charger
ENDURO _4004	Lithium Ultimate AA batteries (x4)
ENDURO_5001	Touch screen computer

DO NOT USE THE PHYSIOFLOW ENDURO WHEN A DEFIBRILLATOR IS CONNECTED TO THE PATIENT. ***THE PATIENT CABLE, THE DEVICE AND THE USB CABLE MUST NEVER COME INTO CONTACT WITH THE PATIENT DURING DEFIBRILLATION****.*

Appendix B : Specifications

Environemental

	Use	Storage	Transport
Temperature	+10 – +34° C	-18°C and + 38°C	-18°C and + 38°C
Humidity	30% – 70%	10% and 70%	10% and 70%
Pressure	700 hPa – 1060 hPa	500hPa – 1060 hPa	500hPa – 1060 hPa

Electric and mechanical

The PhysioFlow device is a Class IIa according to the European directive 93/42/CEE, Appendix IX.

The patient cable should be unplugged from the patient before any use of defibrillator. The enclosure, the disconnected USB and patient cables should not be in contact with the patient when a shock is triggered.

Size	110 x 84 x 16 mm (enclosure only)
Weight	336g with patient cable and without batteries
Communication link	Bluetooth Class 2
Electrical Supply	2 AA batteries (cf. recommended references)
Applied parts	B Type
Patient electric power	Sinusoidal, 66 kHz, < 4.5mA peak to peak

Electromagnetic compliance

Guidance and manufacturer's declaration - electromagnetic emissions		
The PhysioFlow Enduro is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow Enduro should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 1	The PhysioFlow Enduro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PhysioFlow Enduro is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The PhysioFlow Enduro is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow Enduro should assure that it is used In such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The PhysioFlow Enduro is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow Enduro should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601
test level</th><th>Compliance level</th><th>Electromagnetic environment guidance</th></tr>
<tr><td>Disturbances
Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the PhysioFlow Enduro including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = \frac{3,5}{3} \times \sqrt{P}$ 80 MHz to 800 MHz

$d = \frac{7}{3} \times \sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b].
Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PhysioFlow Enduro is used exceeds the applicable RF compliance level above, the PhysioFlow Enduro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PhysioFlow Enduro.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PhysioFlow Enduro

The PhysioFlow Enduro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PhysioFlow Enduro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PhysioFlow Enduro as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80MhZ	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \frac{3,5}{3} \times \sqrt{P}$	$d = \frac{3,5}{3} \times \sqrt{P}$	$d = \frac{7}{3} \times \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.