Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

PHYSIOFLOW® ENDURO™

Service Manual

Monday, 10 July 2017

First placing on the market : 02 October 2008

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Table of contents

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

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:

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
E-mail: support@physioflow.com

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

North America:
NeuMedX
2014 Ford Road, Unit G
Bristol, PA USA 19007
tel: (215) 826 9998
fax: (215) 826 8102

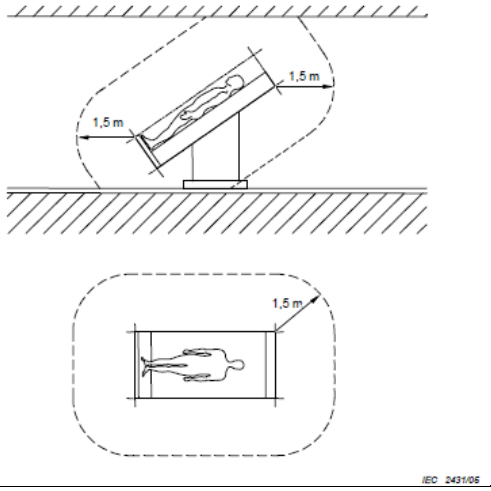
Contact
e-mail: jim.gunnerson@neumedx.com

Other countries/ Rest of the world:
Manatec Biomedical
10 bis, rue Jacob Courant
78300 Poissy - France
tel: +33 (0)3 72 82 50 00
fax: +33 (0)1 30 74 46 48

Contact:
e-mail: sales@physioflow.com
Technical support
e-mail: support@physioflow.com

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Definitions

Patient Environment	Any area in which intentional or unintentional contact can occur between a patient and parts of the medical equipment or between a patient and other persons touching parts of the medical equipment. For the PhysioFlow® application, it equates to a 1.5m distance around the patient himself or of the surface he is in contact with (in any direction). 

Conditions of Use

The PhysioFlow® Enduro is a noninvasive hemodynamic evaluation system using analysis of trans-thoracic bioimpedance signals. The system can be used at rest or while exercising to assess the patient's cardiovascular state either in real time or holster measurement mode.

The PhysioFlow® devices are intended to place the computer out of the patient environment (cf. "*Definitions"* section).

	*If the operator has to install/use the computer within the patient environment, the computer needs to have a medical grade (Comply with IEC 60601-1 standard).*

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Indications

The PhysioFlow® System is indicated for use for patients who meet any of the following criteria:

- Noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular diseases.
- Differentiation of cardiogenic from pulmonary causes of acute dyspnea.
- Optimization of atrioventricular interval for patients with A/V sequential cardiac pacemakers.
- Patients with need of determination for intravenous inotropic therapy.
- Post heart transplant myocardial biopsy patients.
- Patients with a need for fluid management.

Contraindications

The PhysioFlow® system is not intended for use on:

- patients with proven or suspected disease involving severe regurgitation of the aorta.
- patients with minute ventilation (MV) sensor function pacemakers.
- cardiac bypass patients while on a cardiopulmonary bypass machine.
- neonatal patients.

Functions

PhysioFlow® System evaluates/computes the parameters listed in Appendix D.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Measuring Technique Information

Trans-thoracic bio impedance is a technique which quantifies the heart's mechanical activity instead of its electrical activity (ECG). The fundamental theoretical principle of the trans-thoracic bio impedance use the direct measurement of the baseline impedance, the velocity index, the acceleration index, the ventricular ejection time and the heart rate, and the early diastolic filling ratio. These measured parameters are used to compute other hemodynamic parameters.

The PhysioFlow® System determination of the hemodynamic parameters is based on the following principles: the biological tissues, as the muscles, bones, fat and blood each have different electrical properties. Among them all, the blood is the most conductive body tissue in the thorax.

As the circulation is pulsatile and the arterial vessels are supple, the differences of pulsatile blood volume are made at the level of thoracic arterial system, mainly in the aorta, in connection with the ventricular function. This blood volume change makes an electrical conductivity change and consequently a change in the impedance of the thorax against the electrical current. The differences in thoracic electrical impedance are essentially created by changes of velocity and blood volume in the aorta.

Unlike other trans-thoracic bio impedance systems, PhysioFlow® System does not rely on impedance baseline measurements to compute parameters. This tends to reduce the limitations of standard Trans-thoracic bio impedance.

PhysioFlow® system uses a non-invasive technique to determine the Trans-thoracic bio impedance. By performing the analysis of Trans-thoracic bio impedance recordings in association with the ECG signal, PhysioFlow® system provides information related to the cardiac function.

PhysioFlow® system measures the change in impedance by injecting a high frequency alternating electrical current of low magnitude towards the thorax between two electrodes positioned on the neck and another two positioned on xiphoïd process. (Please refer to appendix D, section "Electric and mechanical" for characteristics on emitted current).

The use of a high frequency current eliminates the risk of interference with heart and brain bioelectrical activity. In addition, as the impedance of skin-electrodes is very low at high frequency, tissues will not endure any thermal effects and the patient feels nothing.

By detecting and measuring the difference of thoracic impedance over time, PhysioFlow® System noninvasively measures the systolic volume, the cardiac output and several other hemodynamic parameters. By comparison, thermo dilution measures differences in temperature in function of the time for measuring systolic volume and cardiac output in an invasive way.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Warnings

- **The patient cable and the device are not designed to withstand defibrillation shocks. When defibrillator is used, THE PATIENT CABLE MUST BE UNPLUGGED FROM THE PATIENT. Do not let the device or patient cable be in contact with the patient when the defibrillator is in use.**
- **Prior to any measurement, ensure optimal signal quality is achieved by**
  - Using the electrodes recommended in this manual (cf. Appendix A). PhysioFlow® cannot provide customer support if any other electrode is used.
  - Ensuring the electrodes are not expired, damaged, dry, or used more than 24 hours
  - Preparing carefully patient's skin (preferably using Nuprep Skin preparation gel)
  - Referring to the instructions for attaching leads document
- PhysioFlow® devices are not suitable for use in an oxygen enriched environment or in the presence of flammable anesthetics.
- Sensors must be only positioned on the skin and nowhere else.
- Disposal of this product and/or its accessories shall be made in accordance with all locally enforced laws.
- PhysioFlow® devices should not be used stacked with or close to any other device. If it cannot be avoided, users must ensure that the PhysioFlow® device function properly in this configuration.
- PhysioFlow® devices are designed to evaluate the patient's cardiovascular state. It is not a diagnostic device. The PhysioFlow® parameters shall **NEVER** be used individually or out of context. They must be combined with other parameters measured by other systems (ECG, BP, SPO2, VO2, etc.), together with the clinical valuation of a physician, and never in lieu and place of these.
- PhysioFlow® devices need extra caution regarding electromagnetic compatibility (EMC). It shall be setup and put on regarding the EMC information specified in this service manual of the device.
- Manatec Biomedical considers itself responsible for effects on basic safety, reliability and characteristics of any PhysioFlow® device only if:
  - The relevant room's electrical installation complies with the appropriate requirements, and if
  - The device is used in accordance with the operating instructions.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

	▪ Any modification of any electro medical PhysioFlow® device is forbidden. ▪ PhysioFlow® Enduro is designed to be reliable, effective and mechanically robust. However it must be used with care. ▪ PhysioFlow® devices have no particular protection against the penetration of liquids. Do not allow liquids to get into the device. ▪ Only patient cable provided by PhysioFlow® must be used. Any other use of the patient cable is forbidden. Moreover, it can increase the electromagnetic emissions and reduce the immunity of the device. ▪ Patient cable **PF07-BA-FILT MUST NOT be used while electro surgery tools are operating** since it could cause irreversible damages to the cable and the PhysioFlow® Enduro unit. To prevent this situation to occur PF07-BA-FILT can't be used when PhysioFlow® Enduro is operated by the PhysioFlow® software. However, it may be used with a compatible 3rd party **monitor providing it is not in the presence of electro surgery devices**. ▪ PhysioFlow® devices must not be sterilized. ▪ FOR ACCURATE MEASUREMENTS, IT IS ESSENTIAL THAT THE OPERATOR UNDERSTANDS THE DIFFERENCE BETWEEN ACCEPTABLE SIGNAL AND POOR SIGNAL QUALITY. (cf. PhysioFlow® Software manual, or third party monitor manual).

Precautions

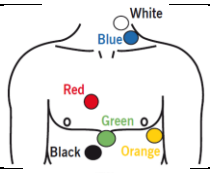
Some clinical circumstances may impair accuracy of measurements, such as:

- Tachycardia with heart rate above 250 bpm
- Untimely movement of neck
- Patients under 120cm (48 in.)
- Patients under 25 Kg (67 lbs.)
- Presence of aortic balloon pumps
- Presence of ultrafiltration systems
- Presence of pacemakers with external leads
- Open chest surgery
- Use of electrical cutlery and electrosurgical devices
- Morbidly obese patients, such as those weighting over 600 pounds.

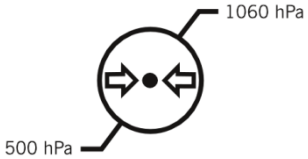
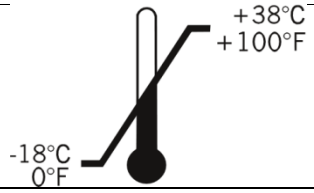
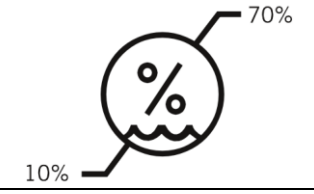
Re-calibration can take place at the same time that the electrodes are replaced as a function of normal nursing protocol. After 24 hours electrodes must be replaced.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
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

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

	Device must be protected from rain
	Symbol of the atmospheric pressure limits that the device can be exposed to.
	Symbol of the temperatures limits that the device can be exposed to.
	Symbol of the humidity limits that the device can be exposed to.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

2. Overall presentation

PhysioFlow® Enduro is a standalone noninvasive cardiac output monitor based on the principle of impedance cardiography. It consists of:

- one handled Bluetooth wireless electronic device. The unit is in charge of acquiring ECG and Impedance signals. Signals are filtered and digitalized before being transferred to the host computer.
- a software – PhysioFlow® V2 – in charge of signal sample collection, signal analysis, hemodynamic values computation (When not in standalone mode), display of results, data storage and printouts.

PhysioFlow® Enduro has two measurement options:

1. Real time: PhysioFlow® software collects data and displays computed physiological parameters in real time.
2. CO holter: the device saves acquired data on an internal memory. Recorded data can then be downloaded by using the PhysioFlow® software.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

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). Battery life: about 7 hours.
  - ✓ Not rechargeable batteries (freshly opened): Energizer Ultimate Lithium AA. Battery life: about 10 hours.
- 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).
-

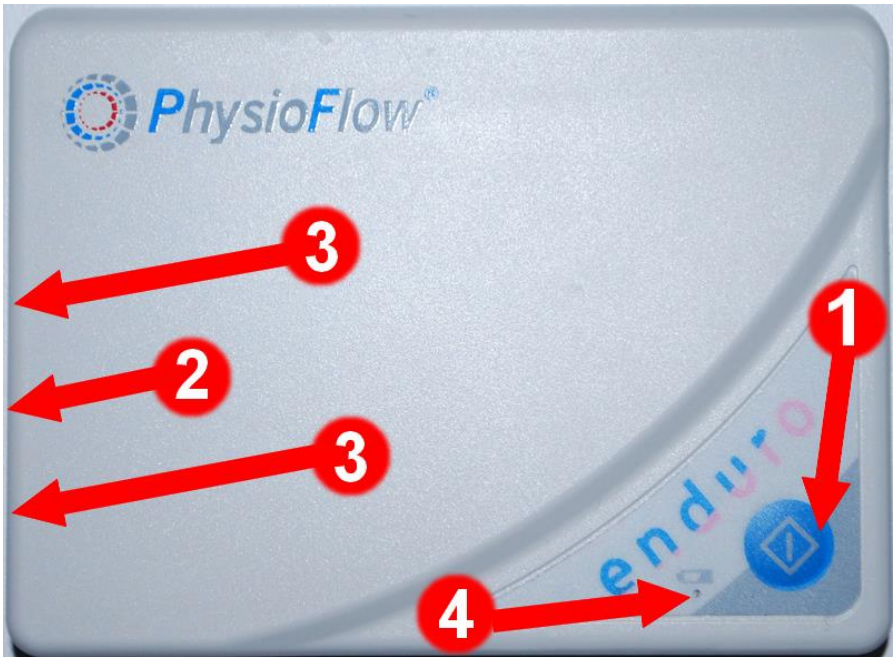
Note: PC requirements are listed in the PhysioFlow® software manual. Please refer to "PhysioFlow® Manual V2" document for more information.

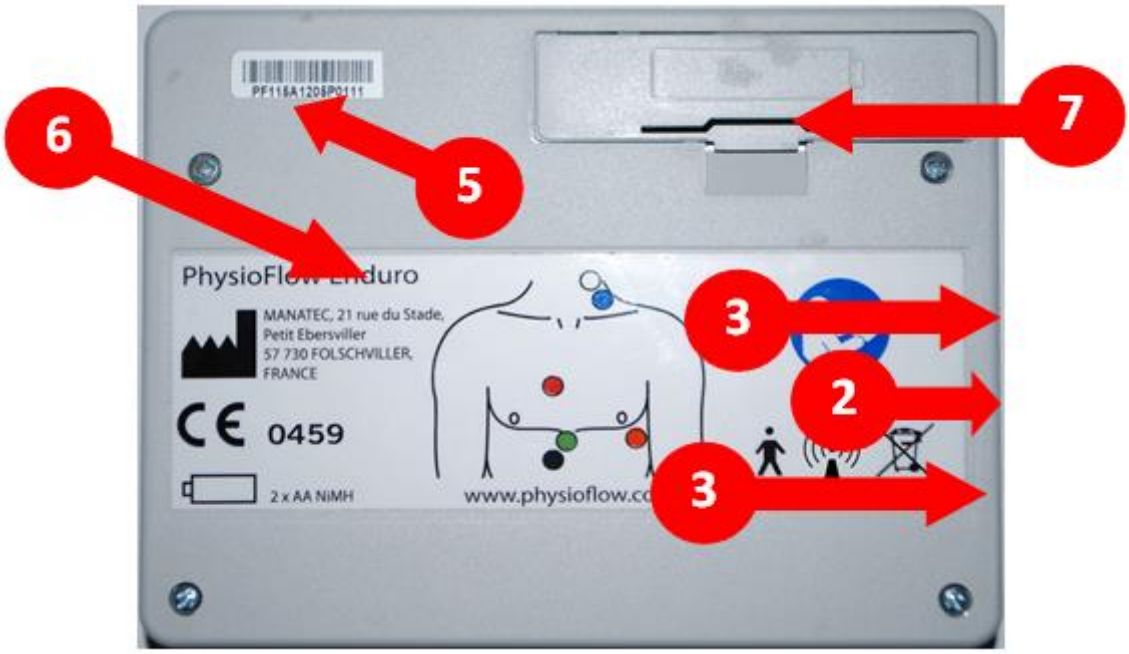
⚠	*Manatec does not support other accessories than the ones listed above.*
	Batteries performances are decreasing over time due to aging and accumulation of charge/discharge cycles. Even if batteries are considered as fully charged following problems could occur: ▪ When Enduro is switched on or monitoring 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.*

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

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.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

5. Device serial number (refer to Appendix C)
6. Sticker with regulatory information (refer to Appendix C)
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.*

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

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.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

4. Maintenance, Transport, Storage and Disposal

Maintenance

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 13.Identification of the PhysioFlow® software V2 for more information). (support@physioflow.com).

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Storage and transport

Please refer to Appendix B for storage and transport environmental conditions.
When the PhysioFlow® is not used, please pack it in the foam padded case in which the device was delivered.

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.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Appendix A: Accessories

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

Designation
Patient cable PF07-BA
Patient cable PF07-BA-FILT (**NOT TO BE USED WHILE ELECTRO SURGERY TOOLS ARE OPERATING**)
PF50 PhysioFlow® Electrodes
Abrasive gel Nuprep
Pouch
1.8m USB cable
Bluetooth dongle with antenna SENA UD100 short distance
Antenna long distance for Bluetooth dongle
AA Rechargeable batteries (x4) & Charger
Lithium Ultimate AA batteries (x4)
Foam padded case

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Appendix B: Specifications

Environnemental

	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	111,9 x 83,9 x 18,3 mm (enclosure only)
Weight	189g 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

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

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.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

<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>

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

(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.

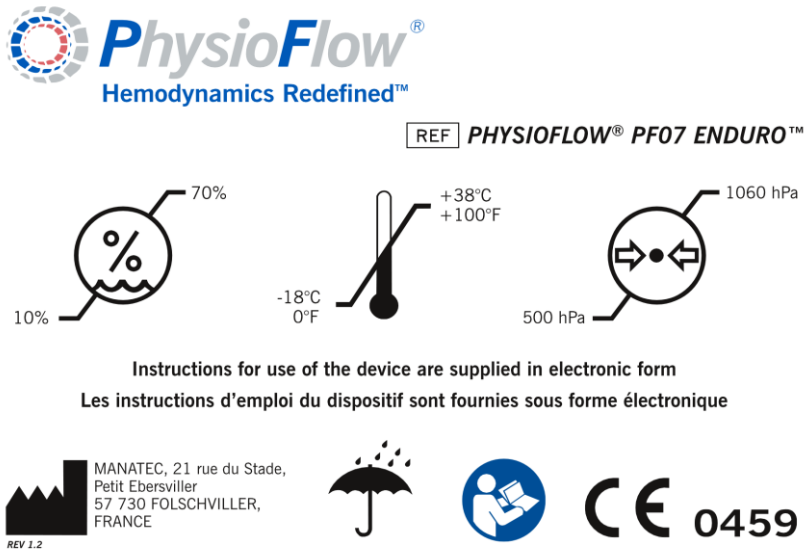
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

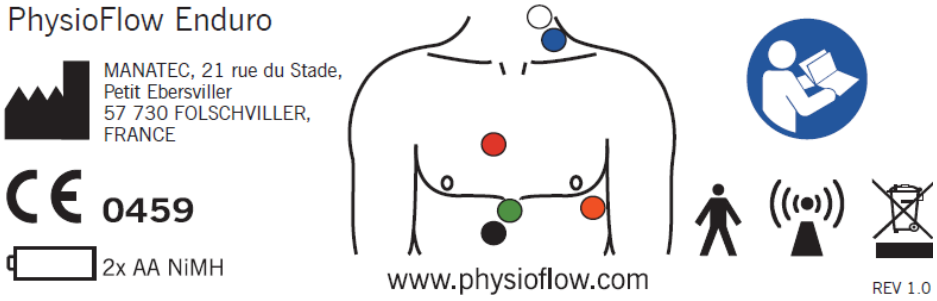
Appendix C: Labels

(For explanations of the symbols, please refer to: Symbols and Marks)

Package label



Enclosure label



Serial number label

(01)03760125071152 (21)AYYMMM0000	1152 : Type of device (Enduro) YYMM : Production date (YY: year; MM: month) 0000 : Product Index, 4 digits In case of after sale services, please provide this 3 fields to the Manatec support. (support@physioflow.com)

Manatec Biomedical
21, Rue du stade, Petit Ebersviller ▪ 57730 Folschviller ▪ France
Tél : +33 (0)3 72 82 50 00 ▪ Fax : +33 (0)1 30 74 46 48
support@physioflow.com

Appendix D: Physiological parameters

This table provides the list of parameters provided by the PhysioFlow® Enduro system.
All these physiological parameters may not be available depending on the device's configuration. If you need to measure one of these parameters which is not available, please contact Physioflow® (support@physioflow.com)

For each parameter are defined:

- Maximal and minimal values. They are based on experience acquired on the PhysioFlow® technology. These ranges are provided to operators as an indication on the technology capabilities.
- Variability. It is the ability of the device to provide the same results +/- the defined variability factor (When used on fix simulated signals, with controlled measurement conditions (30 beats calibration, 15 seconds averaging, patient at rest)).

Parameter	Unit	Low value	High Value	Variability
Heart rate (HR)	bpm	30	215	1%
Stroke Volume (SV)	mL	0	220	5%
Stroke Volume Index (SVi)	mL/m²	0	100	5%
Cardiac Output (CO)	L/min	0	40	5%
Cardiac Index (CI)	L/min/m²	0	20	5%
Contractility Index (CTI)	None	4	3000	5%
Ventricular Ejection Time(VET)	ms	117	499	5%
Ejection Fraction (EF)	%	10	92	5%
End Diastolic Volume (EDV)	mL	0	300	5%
Systemic Vascular Resistance index (SVRi)	Dyn.s/cm^5.m²	0	6000	Refer to Blood pressure user manual
Systemic Vascular Resistance (SVR)	Dyn.s/cm^5	0	3000	
Systolic Arterial Pressure (SAP)[1]	mmHg	20	330	
Diastolic Arterial Pressure (DAP)[1]	mmHg	20	330	
Mean Arterial Pressure (MAP)[1]	mmHg	20	330	
Left Cardiac Work index (LCWi)	kg.m/m²	0	30	
Early Diastolic Filling Ratio (EDFR)	%	8	285	5%
Thoracic Fluid Index (TFi)	Ohm	15	60	5%
Thoracic Fluid Content (TFC)	/kOhm	16	66	5%
Thoracic Fluid Content index (TFCi)	/kOhm/m²	8	33	5%

[1] SAP and DAP are not computed by the PhysioFlow library. Parameters are filled by the operator in the software user interface or automatically imported from compatible blood pressure monitors.