

PHYSIOFLOW[®] ***Enduro***[™]

Service Manual

Thursday, 10 June 2021/ V4.1

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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 can be used in one of the following way:

- with the PhysioFlow[®] Software V2.
- with a compatible third-party monitor. In this case it is not necessary to install the PhysioFlow[®] software. For details on compatibility and instructions for coupling with such a monitor please refer to the respective device IFU, handbook, or manual

This manual is for medical and biomedical staff involved in operating, configuring and handling the system. To this extent initial agent training associated with the reading of the Enduro™ service manual are sufficient for proper and safe use of the system.

Contact









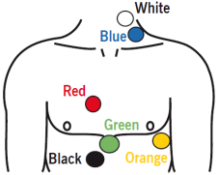
Manatec Biomedical
21, Rue du stade, Petit Ebersviller
57730 Folschviller – France
Phone : +33 (0)3 72 82 50 00
Fax : +33 (0)1 30 74 46 48
Email : support@physioflow.com







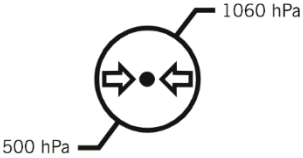
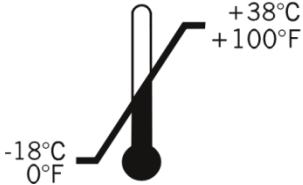

Technical and commercial Information:

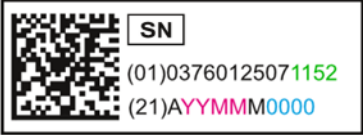
Manatec Biomedical
10 bis rue Jacob Courant
78300 Poissy – France
Tél : +33 (0)3 72 82 50 00
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Commercial contact:
Email : sales@physioflow.com
Technical support:
Email : support@physioflow.com

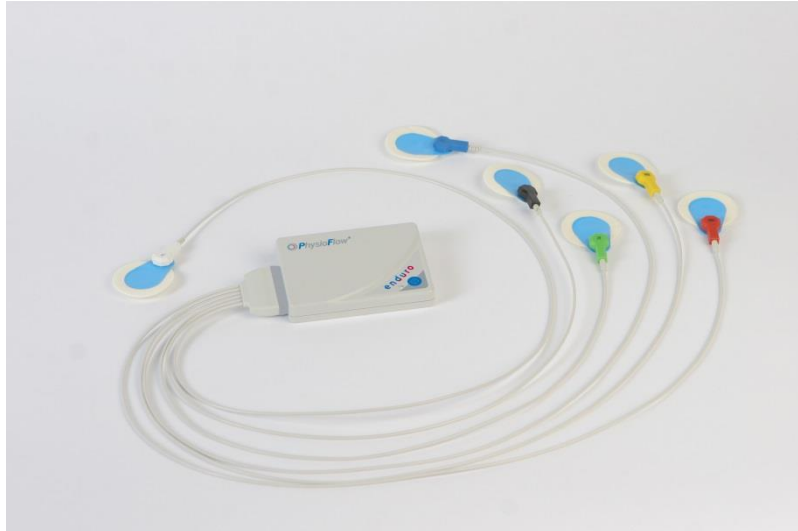
Symbols and Marks

Symbols	Signification
	Refer to instruction manual for the device. Instruction manuals must be read.
	Connections linked to the patient are BF Type.
	Device powered by 2 x AA NiMH batteries.
	The "CE" mark ensures that the device complies with the conformity requirements of the European Directive 93/42/EEC on medical devices, the European Directive 2014/53/EU on radio equipment, and the European Regulation 207/2012/EU on electronic instructions for use of medical devices
0459	Registration number of the organization that ensures that the device complies with the conformity requirements of the European Directive 93/42/EEC on medical devices.
	The Enduro™ product is classified according to the WEEE directive (2012/19/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.

Symbols	Signification
	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.
	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
	Device must be protected from rain.
	Catalogue number.
	Serial number symbol
	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.

Symbols	Signification
 <p>(01)03760125071152 (21)AYMMM0000</p>	<p>Serial number affixed on the device</p> <p>1152: Device type(Enduro™)</p> <p>YMM: Production date (YY: year; MM: month)</p> <p>0000: Product index (4 digits)</p>

2. Device presentation



PhysioFlow[®] Enduro™ is a noninvasive cardiac output evaluation technique, which provides hemodynamic parameters by analyzing transthoracic impedance signal. It can be used at rest or while exercising for a real-time measurement (wireless radio link), or a CO Holter (acquired data are saved on an internal memory).

It consists in an electronic device, connected to a host interface (either a computer or a compatible third-party monitor).

The electronic unit generates high frequency and low amplitude current, digitizes and processes the ECG and modulated thoracic impedance signals. The ECG signal provides a time basis, a trigger for the PhysioFlow[®] algorithm. This ECG signal is not used for electrocardiography analysis.

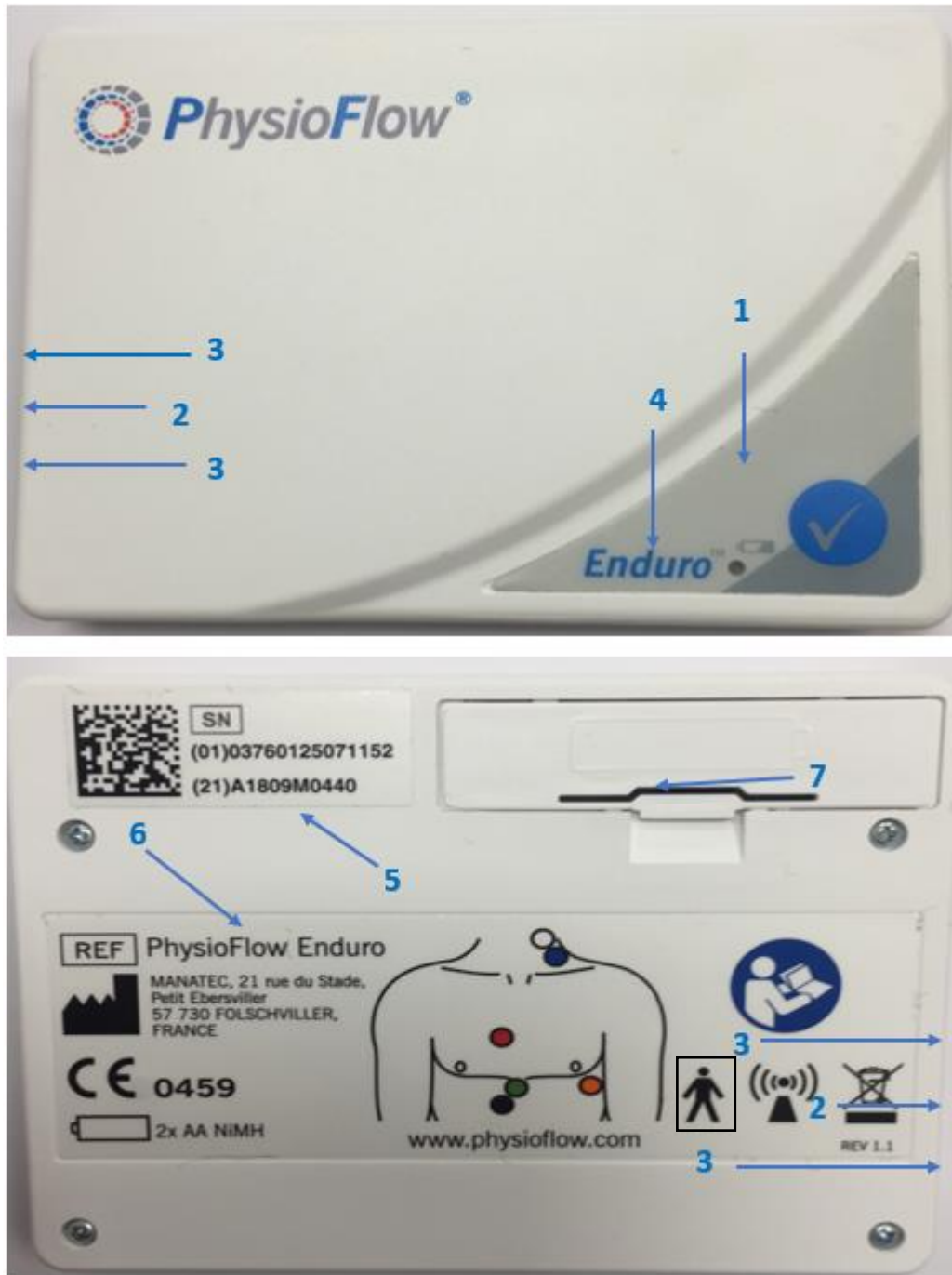
The 6 measuring electrodes and the patient cable are applied parts of type BF according to the definition of IEC 60601-1.

The PhysioFlow[®] software¹ or the compatible host performs electronic unit control, signal sample collection, display of results, data storage and printouts.

¹ For more information about the software, its installation and usage, refer to the following chapters or to the appropriate third-party user manual



Interfaces

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



1. Push button (unused, 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:
 - **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. The operator has to change the batteries.
 - **Detection:** When the software detects Enduro™ devices at range, the device being detected trigger the following color sequence: red/orange/green.
 - **When an acquisition is running:** flashing green.
 - **Device powered and not used / memory download:** constant green.
5. Device serial number.
6. Sticker with regulatory information (refer to section “[Symbols and Marks](#)”).
7. Batteries compartment. The battery compartment cover gives direction regarding the polarity for correct insertion.

	Do not open the enclosure.
	<p>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:</p> <p style="text-align: center;">  </p> <p>Do not force the USB cable with another type of port.</p>

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.

Precautions

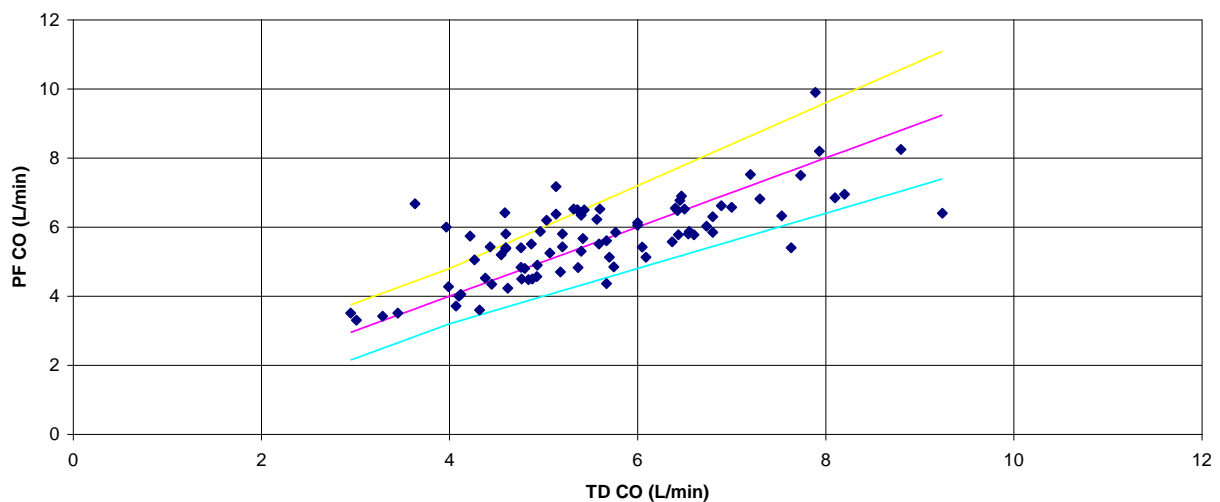
Some clinical circumstances may impair accuracy of measurements, such as:

- 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 (IABP),
- Presence of ultrafiltration systems,

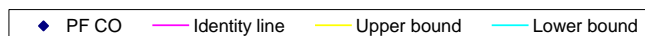
- Presence of pacemakers with external leads,
- Open chest surgery,
- Use of electrical cutlery and electrosurgical devices,
- Morbidly obese patients, such as those weighting over 272kg/600 pounds.

As per US FDA's requirements, please take note of the following graph comparing PhysioFlow[®] cardiac output readings to Thermodilution cardiac output readings. It shows that 82% of readings are within bounds (20% = margin of error of thermodilution).

**K060387 PF CO vs. TD CO, (PF 4 of 4)
Manufacturer data
15/84 = 18% of data are outside bounds**



Each PF reading was an average (avg.) of 4 consecutive readings, and each TD reading was an avg. of the best 3 of 4 readings, except that if the 2 extremes of the 4 TD readings were equidistant from the avg., the avg. of all 4 was used.



Functions

PhysioFlow[®] System evaluates/computes the parameters listed in [Appendix C](#).

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 HTFS50PF electrodes (cf. [Appendix A](#)). Manatec 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
- Do not 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.
- The PhysioFlow[®] Enduro™ is a noninvasive hemodynamic evaluation system to assess patient cardiovascular state using analysis of trans-thoracic bioimpedance signals. It can't be used alone to detect the cause of a given physiological or pathological condition. Thus, PhysioFlow[®] parameters and their variations shall **NEVER** be used individually or out of context. They must be combined with other parameters measured by other systems (BP, ECG, 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.
- 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 can 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. (refer to PhysioFlow[®] Software indications, or third-party monitor manual).
- Enduro™ is not intended to be in contact with the patient in normal use.
- PhysioFlow[®] Enduro™ device does not claim any essential performance under 60601-1 standard".
- The Enduro™ purse and belt are not designed to be in contact with the patient in normal use. They should be worn over the patient's clothing.
- It is recommended to leave as much as possible the enduro in its pouch, with the patient cable connected.
- The battery cover must be closed before using the unit.

3. Device Installation

Minimum configuration requirements

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): Ansmann 2850mAh (ref. 5035092). 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).

	<p><i>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:</i></p> <ul style="list-style-type: none"> ▪ When Enduro™ is switched on or monitoring is launched, the device is tested: <i>the boot sequence fails (LED indicator turns to red).</i> ▪ <i>Enduro™ / PC Bluetooth connection problems.</i> ▪ <i>Measurement session does not last as long as expected.</i> <p><i>In this case it is recommended to buy new batteries locally and recycle old batteries at sales points, any local recycling center or the battery manufacturer. For more information please refer to local regulation or battery manufacturer instructions.</i></p>
	<p><i>The batteries should be removed from the device when you do not intend to use it. Acid leaks may damage the unit irreparably.</i></p>
	<p><i>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.</i></p> <p><i>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.</i></p>
	<p><i>If the host is a computer/laptop, it must, as a minimum requirement, be graded class II and comply with the relevant standard for information-processing equipment (IEC 60950-1).</i></p> <p><i>If the operator has to install/use the computer within the patient environment², the class II computer needs to comply with applicable medical standards.</i></p>

² Volumetric area in which a patient can come into contact with medical equipment or contact can occur between other persons touching medical equipment and the patient, both intentional and unintentional

For a correct installation and use of the software, the computer must have at least the following characteristics:

- Operating system: Microsoft Windows 7, 8, 10.
- 2GHz dual core X86 or X64 Processor.
- 4GB RAM.
- 250MB Free hard disk space for installation.
- Minimal size screen advised: 15" (1280 x 768).

	<p>10GB free space on the hard drive is recommended to store monitoring data. User has to make sure to have enough disk space for every measurement session! If the disk space is less than 250MB, a warning indicates that the user should stop using the software and free 10GB.</p>
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Installation


PhysioFlow Software V2, open the setup of the PhysioFlow[®] software (available on the installation CD, the USB key, or a link given by PhysioFlow[®] support support@physioflow.com). Follow the steps listed on screen.

The hardware installation process is limited to Enduro™ communication interfaces:

- Wireless Bluetooth connection through Sena UD100 Bluetooth antenna.
- USB interface when the Enduro™ is plugged to the host.

Once the drivers are installed communication link is automatically configured when PhysioFlow[®] software is launched.


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

	<p>In some cases automatic detection will not work so users have to make sure that:</p> <ul style="list-style-type: none"> - Only accessories listed below are used. - the device is turned ON. - the drivers are installed properly. - The computer does not have an internal Bluetooth antenna. In this case user has to uninstall this internal antenna and drivers. - PhysioFlow[®] only supports Microsoft Bluetooth drivers. All other drivers like Toshiba, WidComm, BlueSoleil etc. are not supported.
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Note (PhysioFlow[®] software 2.8.0 and later) Some features are subject to license. The user must enter the license key in the software, then enter the activation code matching the license and the computer. For this, please contact the local distributor to get a new license key, and contact the technical support (support@physioflow.com) to get a new activation code.

Starting a measurement

In order to switch the device on, the operator has to open the battery cover with a 2.5mm flat screwdriver before inserting the batteries. The software shows to the user the recommendations to follow before the measurement starts.

	It is important to strictly follow the instructions regarding skin preparation and electrode placement listed in the document « Instructions for attaching leads».
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Stop Procedure

If a measurement is in progress, the measurement should be stopped by pressing the dedicated button on the PhysioFlow software or compatible monitor. Then, the batteries should be removed from the Enduro™.

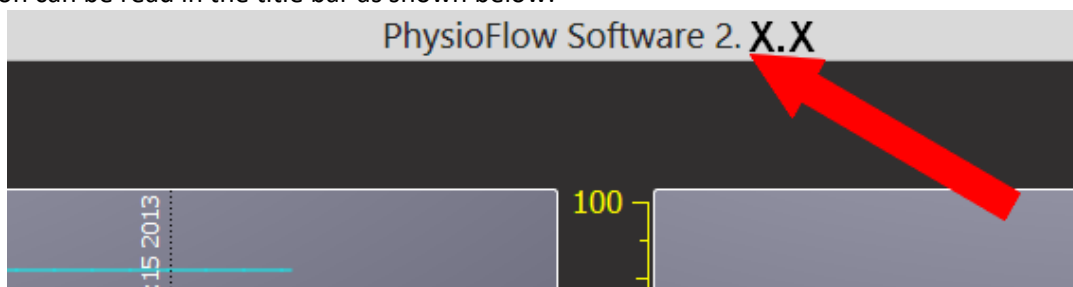
4. Identification and update of software

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 (support@physioflow.com).

Identification of the PhysioFlow[®] software V2

To know the version of the PhysioFlow[®] software installed on the computer, launch the software by double clicking on the desktop shortcut “PhysioFlow[®] Software”. Once the software is launched the version can be read in the title bar as shown below:



Software update

The update of PhysioFlow[®] software 2 is performed by an installation program. The installation of a new software version replaces the existing version, but does not impact the data stored on the computer.

The software detects automatically the devices at range/connected, and informs the operator when the device needs a firmware update. The associated procedure is started when the user presses the “Update Firmware”.

Note: The firmware associated with the new PhysioFlow[®] software 2 is not compatible with the previous generation v107 software.

5. Maintenance, Transport, Storage and Disposal

Maintenance


Hardware

The Enduro™ does not need any calibration or service operation during normal use.

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 host while cleaning. If the system has been contaminated by blood or body fluids, clean and disinfect as specified in the instructions supplied with the patient cable.

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

	<p>Any maintenance and service operations must only be carried out by Manatec Biomedical.</p> <p>The enclosure must not be opened by the user (operator and technician).</p>
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Software

It is strongly recommended to back up the database regularly to prevent any data loss in case of PC crash or hard drive failure. The instructions are available on the [PhysioFlow® software 2 knowledge base](#).

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 2012/19/EU (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

Host: 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 according to the local law and/or procedure used in the facility.

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)
Electrodes HTFS50PF
Abrasive gel Nuprep [®]
Pouch with waist belt and holster
1.8m USB cable
Bluetooth SENA UD100 dongle with short distance antenna
Long distance antenna for Bluetooth SENA UD100 dongle
AA Rechargeable batteries (x4) & Charger
Lithium Ultimate AA batteries (x4)
Foam padded case
PhyioFlow [®] USB drive
Information leaflet about user instructions

Appendix B: Specifications

Environmental

	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[®] Enduro™ is a Class IIa according to the European directive 93/42/CEE, Appendix IX.

Size	110 x 84 x 16 mm (enclosure only)
Weight	189g with patient cable and without batteries
Communication link	Bluetooth BR/EDR, Power <= 10dBm
Electrical Supply	2 AA batteries (cf. recommended references)
Applied parts	BF 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	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 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.

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
Disturbances Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	3V	<p>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.</p> <p>Recommended separation distance</p> $d = \frac{3,5}{3} \times \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{3} \times \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Disturbances Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10V/m	
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.		

- (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 80MHzZ	80 MHz to 800 MHz	800 MHz to 2,7 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.

Appendix C: 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. Please contact Physioflow® (support@physioflow.com) for more information

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/m ²	0	100	5%
Cardiac Output (CO)	L/min	0	40	5%
Cardiac Index (CI)	L/min/m ²	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 .m ²	0	6000	Refer to Blood pressure user manual
Systemic Vascular Resistance (SVR)	Dyn.s/cm ⁵	0	3000	
Systolic Arterial Pressure (SAP) ³	mmHg	20	330	
Diastolic Arterial Pressure (DAP) ³	mmHg	20	330	
Mean Arterial Pressure (MAP) ³	mmHg	20	330	
Left Cardiac Work index (LCWi)	kg.m/m ²	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/m ²	8	33	5%

³ 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.