

PHYSIOFLOW[®] Q-LINK™

Service Manual

Thursday, 08 March 2018

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Service Manual PhysioFlow[®] Q-Link™

1. General Information

About this manual

This manual contains all the required information for installation, use, maintenance, transport and storage operations for the PhysioFlow[®] Q-Link™ 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 Q-Link™ service manual are sufficient for proper and safe use of the system.

Contact



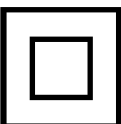
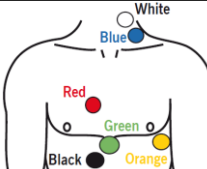
Manatec Biomedical
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Phone : +33 (0)3 72 82 50 00
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Email : support@physioflow.com

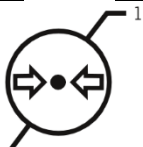
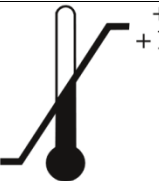
Technical and commercial Information:

Manatec Biomedical
10 bis rue Jacob Courant
78300 Poissy – France
Tél : +33 (0)3 72 82 50 00
Fax : +33 (0)1 30 74 46 48

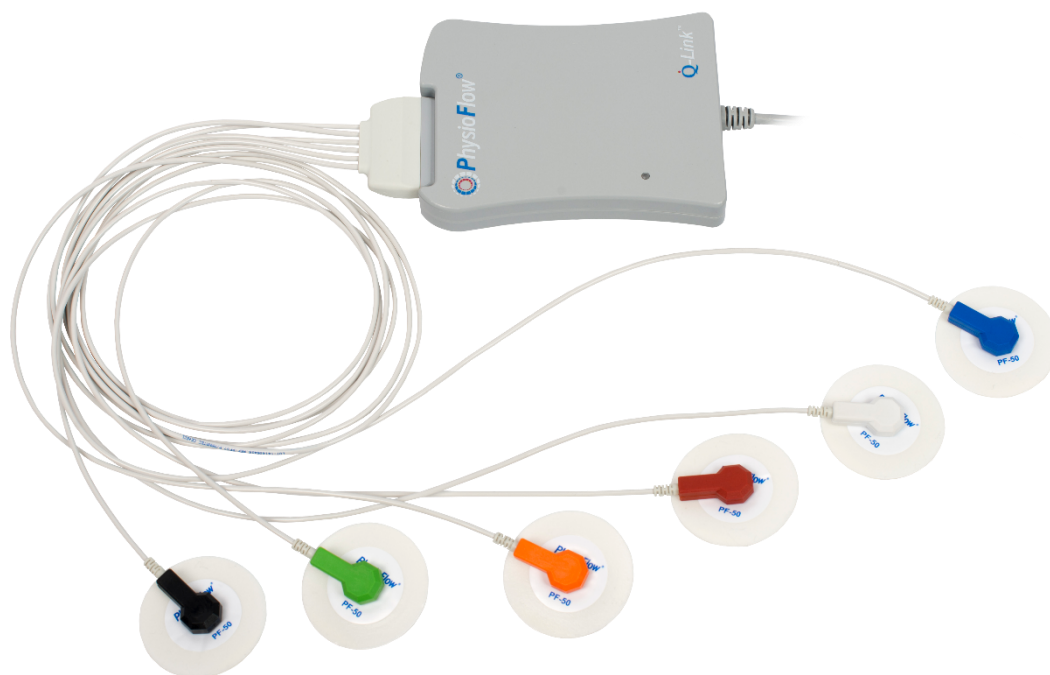
Commercial contact:
Email : sales@physioflow.com
Technical support:
Email : support@physioflow.com

Symbols and Marks

Symbols	Signification
	Refer to instruction manual for the device. Instruction manuals must be read.
	PhysioFlow [®] Q-Link™ is a CLASS II device according to the IEC 60601-1 standard.
	Connections linked to the patient are BF Type.
	Device powered by a continuous current source.
	« 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 Q-Link™ 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)
	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.
	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

Symbols	Signification
	Device must be protected from rain
	Catalogue number
	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.
 (01)03760125071213(21)AYYMM0000	Serial number affixed on the device 1213: Device type(Q-Link™) YYMM: Production date (YY: year; MM: month) 0000: Product index (4 digits)

2. Device presentation



PhysioFlow[®] Q-Link™ 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.

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

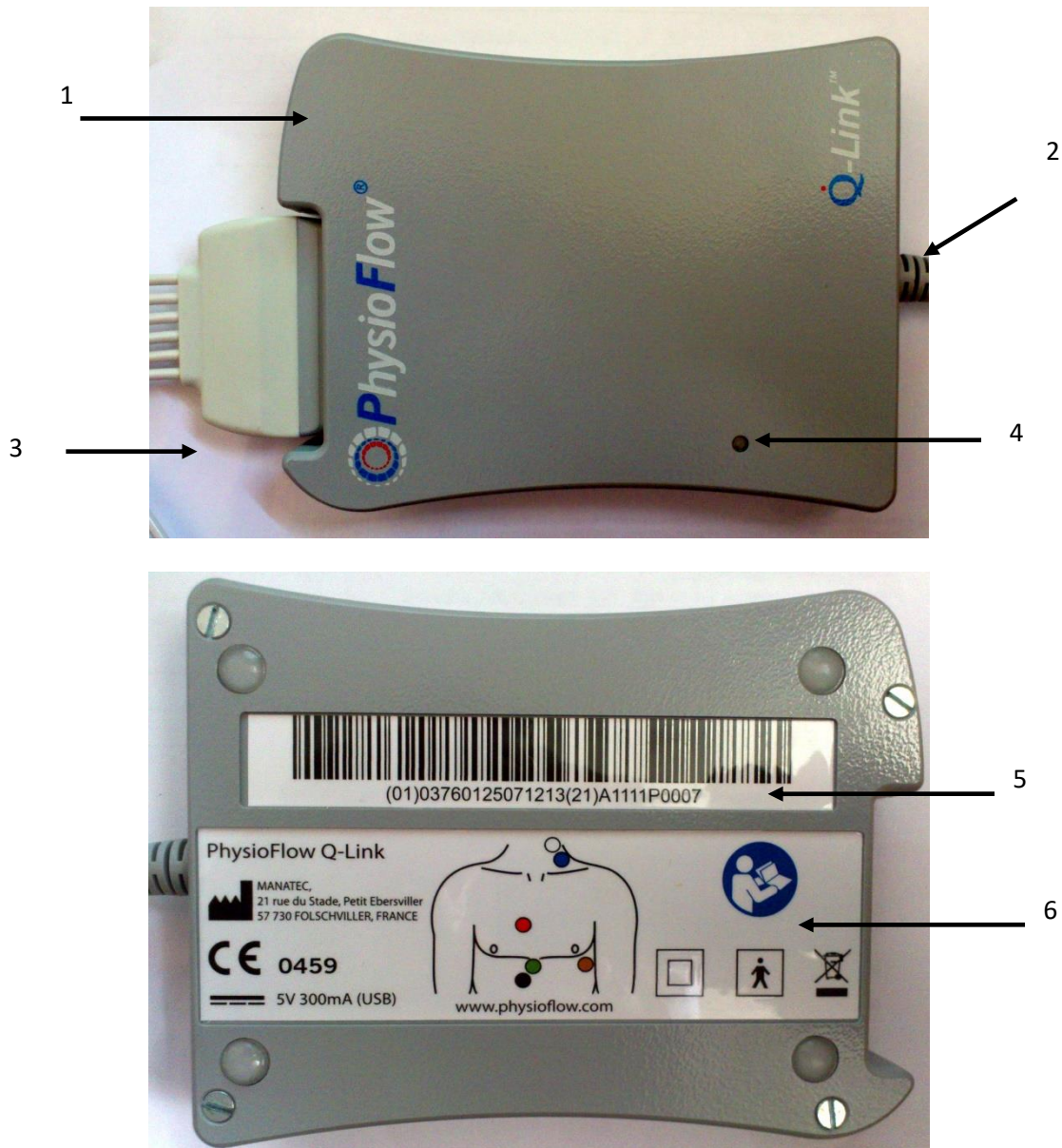
The electronic unit generates high frequency and low amplitude current, digitizes and processes the ECG and modulated thoracic impedance signals. The ECG signal provides a time basis, a trigger for the PhysioFlow algorithm. This ECG signal is not used for electrocardiography analysis

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



1. Ergonomic case makes it easy to handle.
2. USB cable to connect to the host.
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, indicating to the user to disconnect the device (the selected USB port fails to deliver the required power and must not be used). The operator has to connect PhysioFlow® Q-Link™ to another USB interface or an external powered USB hub.
 - **Detection:** When the software detects the connected Q-Link™ devices, the device being detected trigger the following color sequence: red/orange/green.

- **When an acquisition is running**: flashing green.
 - **Device powered and not used**: constant green.
5. Device serial number.
 6. Sticker with regulatory information (refer to section “[Symbols and Marks](#)”).

	When the device is used, the operator must pay attention to the USB cable between the Q-Link™ and the host to prevent any risk of fall and/or degradation of the system. Do not install the system in a crowded area.
	Do not open the enclosure.
	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/outlet.
	In case of a communication error between the host and the Q-Link™ system, the USB interface has to be unplugged and re-plugged to restart and reinitialize the device.

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.

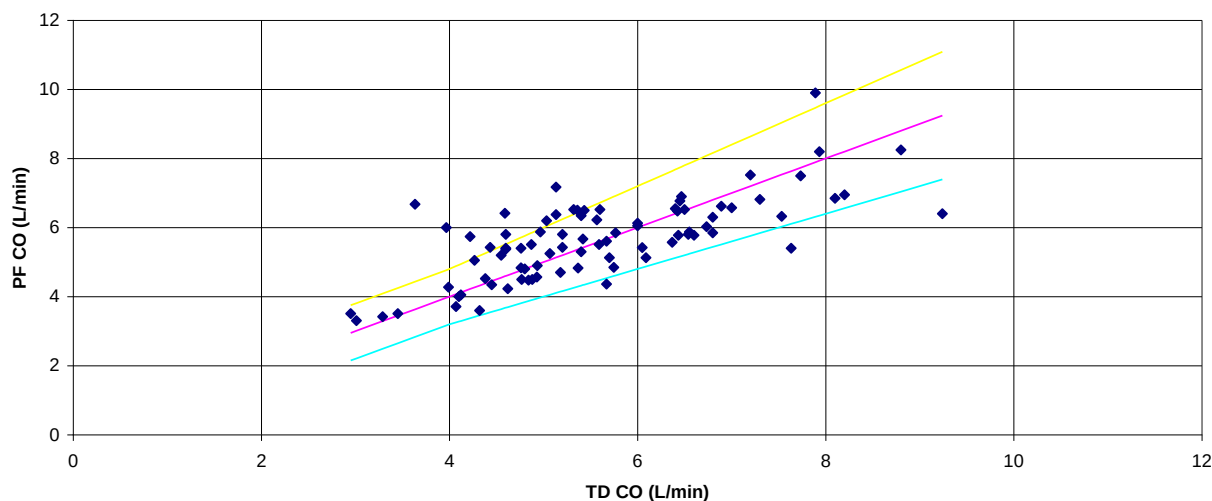
Precautions

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

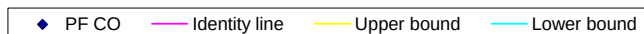
- tachycardia with heart rate above 250 bpm,
- untimely movement of neck,
- patients under 120cm (48 in.),
- patients under 25 Kg (67 lbs.),
- presence of aortic balloon pumps,
- presence of ultrafiltration systems,
- presence of pacemakers with external leads,
- open chest surgery,
- use of electrical cutlery and electrosurgical devices,
- morbidly obese patients, such as those weighting over 600 pounds.

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 PhysioFlow[®] PF-50 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[®] Q-Link™ 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 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.

- | | |
|--|---|
| | <ul style="list-style-type: none"> ▪ PhysioFlow[®] Q-Link™ 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[®] Q-Link™ unit. To prevent this situation to occur PF07-BA-FILT can't be used when PhysioFlow[®] Q-Link™ 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). ▪ The Q-Link™ device must be operated on a non-tilted table. ▪ Q-Link™ is not intended to be in contact with the patient in normal use. |
|--|---|

3. Device Installation

Minimum configuration requirements

In order for the Q-Link™ to work properly, the host (computer or third party medical system) must have an available USB port to supply power to the device and to allow communication. Minimal power source requirements are: 5V +/- 500mV, 300mA.

	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). If the operator has to install/use the computer within the patient environment², the class II computer needs to comply with applicable medical standards. The USB standard requires minimum performances in terms of power (5V, 500mA max). However, the power delivered by the computer may not be sufficient enough. In this case, the user may use a USB hub with an external power supply.
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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)

	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.
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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.

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 Q-Link™ is an USB « Plug and Play » device. This means the system is automatically detected and installed when the USB is connected to the host.

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

Notes:

- 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.
- The PhysioFlow[®] Q-Link™ for Deltex is not intended to be used with the PhysioFlow[®] Software. Please refer to Deltex medical's CardioQ-ODM user manual for more information regarding ODM / PhysioFlow[®] Q-Link™ system configuration and use.

Starting a measurement

The procedure is given in the quick start guide provided with the device. As a complement, 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».

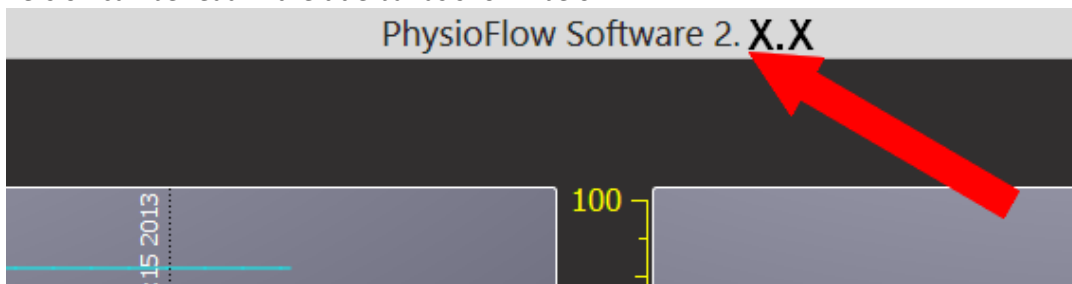
4. Identification and update of software

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

1.1.1 Hardware

The Q-Link™ 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 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
Q-Link™ 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).
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2.1.1 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[®] Q-Link™ device: Do not throw away. Some components can be recycled according to European Directive 2012/19/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

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 PhysioFlow [®] PF-50
Abrasive gel Nuprep [®]
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[®] Q-Link™ is a Class IIa according to the European directive 93/42/CEE, Appendix IX.

Size	126 x 97 x 19 mm (enclosure only)
Weight	369g (patient and USB cables)
Length of the USB cable	298cm +/-10%
Electrical Supply	5V, 300mA
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 [®] Q-Link™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow [®] Q-Link™ should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment- guidance
RF emissions CISPR 11	Group 1	The PhysioFlow [®] Q-Link™ 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	
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 [®] Q-Link™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow [®] Q-Link™ 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	± 1 kV for input/output lines	± 1 kV for input/output lines	
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® Q-Link™ is intended for use in the electromagnetic environment specified below. The customer or the user of the PhysioFlow® Q-Link™ 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 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the PhysioFlow® Q-Link™ 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: 
		3V/m	
Disturbances Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		
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[®] Q-Link™ is used exceeds the applicable RF compliance level above, the PhysioFlow[®] Q-Link™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PhysioFlow[®] Q-Link™.

(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[®] Q-Link™

The PhysioFlow[®] Q-Link™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PhysioFlow[®] Q-Link™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PhysioFlow[®] Q-Link™ 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.

Appendix C: Physiological parameters

This table provides the list of parameters provided by the PhysioFlow[®] Q-Link™ 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.