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® Q-LINK™

Service Manual

Thursday, 20 October 2016

First placing on the market : 18 January 2012

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
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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 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

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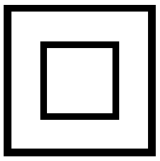
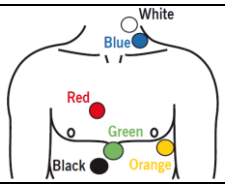
Symbols and Marks

Symbol	Signification
	Refer to instruction manual for the device and the software. 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 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 Q-Link 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)
	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

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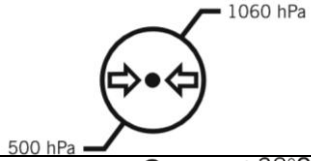
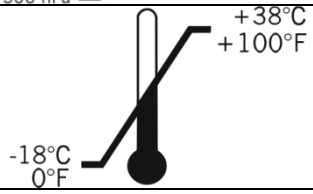
	Device must be protected from rain
	Symbol of the atmospheric pressure limits that the device can be exposed to.
	Symbol of the temperatures limits that the device can be exposed to.
	Symbol of the humidity limits that the device can be exposed to.

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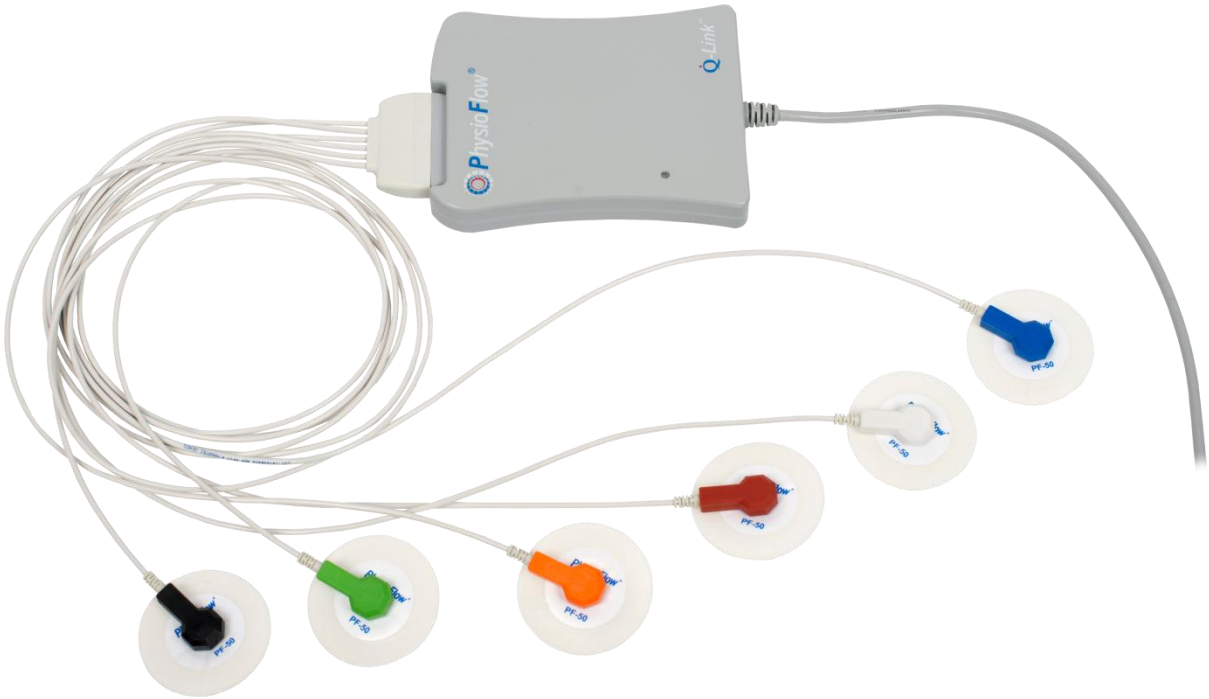
2. Overall presentation



PhysioFlow Q-Link is a portable noninvasive cardiac output monitor. It consists in an electronic device, connected to a PC compatible computer through a USB link. It is based on the principles of impedance cardiography.

The electronic unit performs impedance signal generation, reception of chest impedance modulated signal, analog and digital filtering, and digitization of signal. And ECG signal is also recorded and digitized. It is used for time basis and heart rate computation.

A Windows based software performs signal sample collection, signal analysis, hemodynamic values computation, display of results, data storage and printouts.

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3. Device Installation: The Q-Link System

Minimum configuration requirements / Accessories

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

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

	*The computer used, as a minimum requirement, must 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 environment[1], 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.*

[1] 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.

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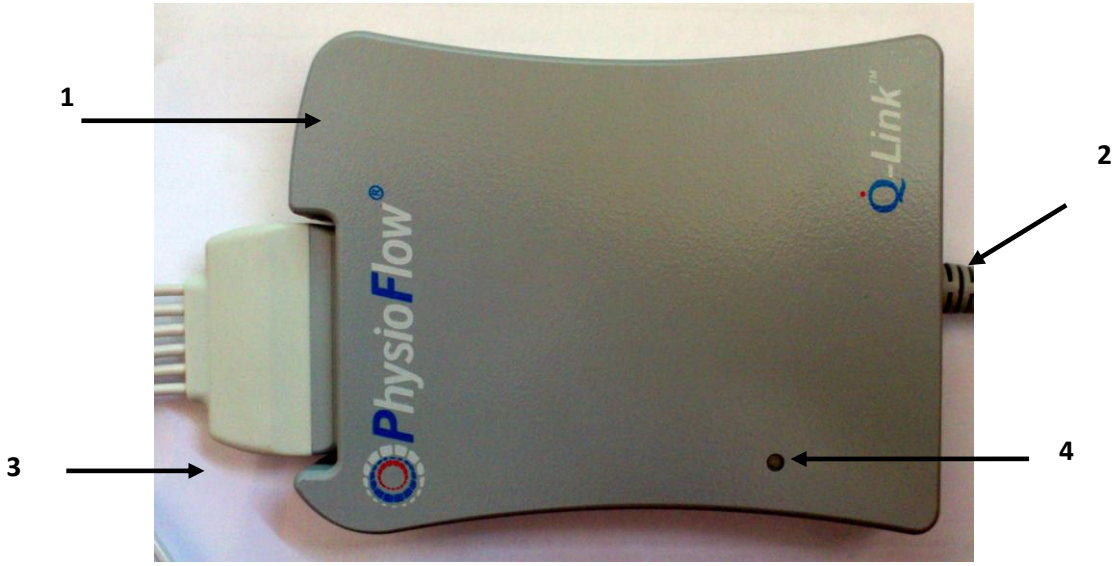
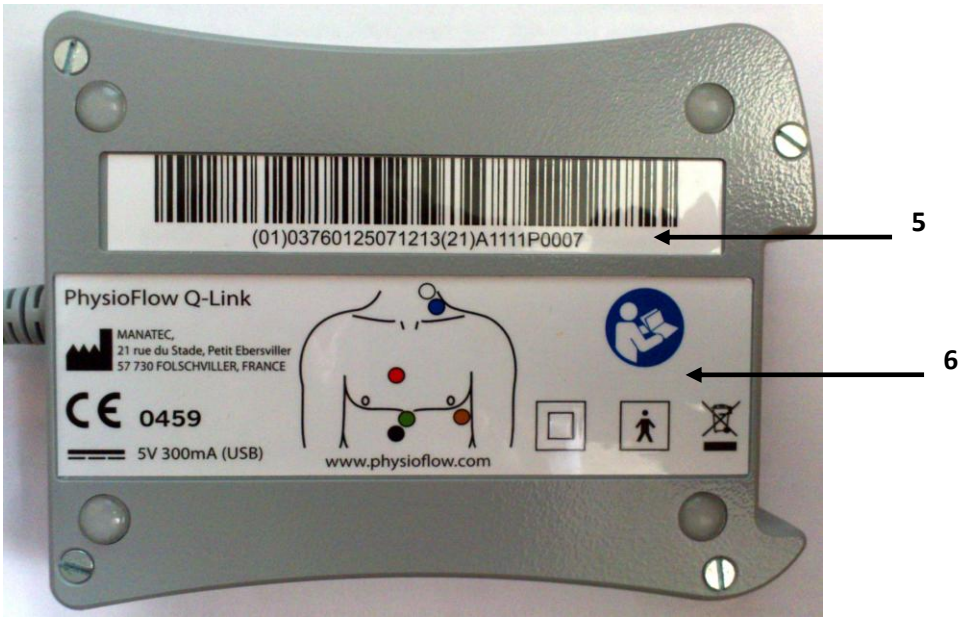
Interfaces

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





1. Ergonomic case makes it easy to handle
2. USB cable to connect to the computer
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, 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
5. Device serial number (refer to Appendix C)
6. Sticker with regulatory information(refer to Appendix C)

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	*When the device is used, the operator must pay attention to the usb cable between the Q-Link and the computer to prevent any risk of fall and/or degradation of the system. Do not install the system in a crowded area.*
	The USB power cable is permanently installed. Maintenance operations regarding this accessory must only be performed by Manatec Biomedical's technical service. *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.*
	The operator can easily isolate the Q-link from the network by simply disconnecting the USB connector from the computer. The computer and the Q-Link have to be installed in a way to ensure an easy access to the USB interface.
	In case of a communication error between the host PC and the Q-link system, the USB interface has to be unplugged and re-plugged to restart and reinitialize the device.

Installation

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

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4. Maintenance, Transport, Storage and Disposal

Maintenance

The Q-Link 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
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).* *No modification of the equipment is allowed.*

Identification of the embedded software version

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

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Storage and transport

When it is not used, the PhysioFlow device must be stored at an ambient temperature between -18°C and +38°C, a relative humidity between 10 % and 70 %, and an atmospheric pressure between 500 hPa and 1060 hPa.
When the PhsyioFlow is not used, please pack it in the foam padded cardboard box that the device was delivered in.

Disposal

PhysioFlow Q-Link 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.

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Appendix A: Accessories

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

Designation
Patient cable
Electrodes PhysioFlow PF-50
Abrasive gel Nuprep
USB cable (Can only be changed by the technical service of Manatec Biomedical).

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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	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

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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.

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<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</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 Conducted RF
IEC 61000-4-6

Disturbances Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2,5 GHz</td><td>3V

3V/m</td><td>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

$d = \frac{3,5}{3} \times \sqrt{P}$
$d = \frac{3,5}{3} \times \sqrt{P}$ 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>

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(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.

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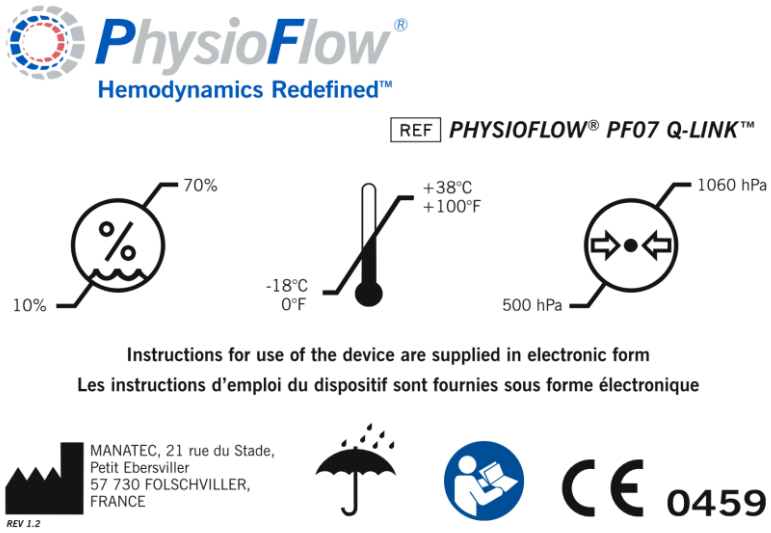
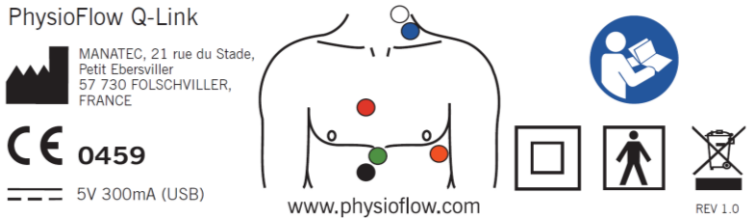
Appendix C: Labels

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

Package label



Enclosure label



Serial number label

1213: Type of device (Q-Link)
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)