PHYSIOFLOW® Q-LINK™

Service Manual

Wednesday, 01 February 2017

First placing on the market: 18 January 2012
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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. In this case refer to user manual dedicated to the PhysioFlow Software V2
- with a compatible third party monitor. In this case it is not be necessary to upload the software. For details on compatibility and instructions for coupling with such a monitor please refer to the respective device IFU, handbook, or manual

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
Definitions

Patient Environment
Any area in which intentional or unintentional contact can occur between a patient and parts of the PhysioFlow system or between a patient and other persons touching parts of the PhysioFlow system. 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 Q-Link 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.

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).
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.
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 xiphioid 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.
**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.
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.
## Symbols and Marks

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Signification</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="symbol.png" alt="User Icon" /></td>
<td>Refer to instruction manual for the device and the software. Instruction manuals must be read.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Class II Device" /></td>
<td>PhysioFlow Q-Link is a CLASS II device according to the IEC 60601-1 standard.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Connection Icon" /></td>
<td>Connections linked to the patient are BF Type.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Continuous Current Source" /></td>
<td>Device powered by a continuous current source.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="CE Mark" /></td>
<td>« 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.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Disposal Icon" /></td>
<td>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)</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Placement Icon" /></td>
<td>Placement of the electrodes.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Warning Icon" /></td>
<td>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.</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Important Icon" /></td>
<td>Important information to consider for an efficient and optimized use of the system.</td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Umbrella" /></td>
<td>Device must be protected from rain</td>
</tr>
<tr>
<td><img src="image" alt="Pressure Meter" /></td>
<td>Symbol of the atmospheric pressure limits that the device can be exposed to.</td>
</tr>
<tr>
<td><img src="image" alt="Temperature Meter" /></td>
<td>Symbol of the temperatures limits that the device can be exposed to.</td>
</tr>
<tr>
<td><img src="image" alt="Humidity Meter" /></td>
<td>Symbol of the humidity limits that the device can be exposed to.</td>
</tr>
</tbody>
</table>
2. Overall presentation

PhysioFlow Q-Link is a portable noninvasive cardiac output monitor. It consists in an electronic device, connected to host interface (either a computer or a compatible third party monitor) 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. An ECG signal is also recorded and digitized. It is used for time basis and heart rate computation.

A Windows based software or compatible host software interface performs signal sample collection, display of results, data storage and printouts.
3. Device Installation: The Q-Link System

**Minimum configuration requirements / Accessories**

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.

*Note:* If the host is a computer/laptop, PC requirements are listed in the PhysioFlow software manual. Please refer to “PhysioFlow Manual V2” document for more information.

<table>
<thead>
<tr>
<th>Warning:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
</tr>
<tr>
<td>If the operator has to install/use the computer within the patient environment¹, the class II computer needs to comply with applicable medical standards.</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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.
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 host
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)
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.

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:

![USB 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 host. The host 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 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 host.

If there are any problems or questions with the installation of the device, please contact technical support: support@physioflow.com.
4. Maintenance, Transport, Storage and Disposal

**Maintenance**

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 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:

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Life Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient cable</td>
<td>2 years from the date of first use</td>
</tr>
<tr>
<td>Q-Link system</td>
<td>7 years from the date of first use</td>
</tr>
<tr>
<td>Electrodes</td>
<td>Single use only. Expiration date is printed on the pouch</td>
</tr>
</tbody>
</table>

Any maintenance and service operations must only be carried out by Manatec Biomedical.

The enclosure must not be opened by the user (operator and technician).

No modification of the equipment is allowed.

**Identification of the embedded software version**

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

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 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

**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.
Appendix A: Accessories

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

<table>
<thead>
<tr>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient cable PF07-BA</td>
</tr>
<tr>
<td>Patient cable PF07-BA-FILT (NOT TO BE USED WHILE ELECTRO SURGERY TOOLS ARE OPERATING)</td>
</tr>
<tr>
<td>Electrodes PhysioFlow PF-50</td>
</tr>
<tr>
<td>Abrasive gel Nuprep</td>
</tr>
<tr>
<td>USB cable (Can only be changed by the technical service of Manatec Biomedical).</td>
</tr>
<tr>
<td>Foam padded case</td>
</tr>
</tbody>
</table>
Appendix B: Specifications

Environmental

<table>
<thead>
<tr>
<th></th>
<th>Use</th>
<th>Storage</th>
<th>Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>+10 – +34°C</td>
<td>-18°C and +38°C</td>
<td>-18°C and +38°C</td>
</tr>
<tr>
<td>Humidity</td>
<td>30% – 70%</td>
<td>10% and 70%</td>
<td>10% and 70%</td>
</tr>
<tr>
<td>Pressure</td>
<td>700 hPa – 1060 hPa</td>
<td>500hPa – 1060 hPa</td>
<td>500hPa – 1060 hPa</td>
</tr>
</tbody>
</table>

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
## 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.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>flicker emissions IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 6 kV contact/± 8 kV air</td>
<td>± 6 kV contact/± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>± 1 kV for input/output lines</td>
<td>± 1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
# 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disturbances</td>
<td>IEC 61000-4-6</td>
<td></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.</td>
</tr>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3V</td>
<td><strong>Recommended separation distance</strong></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2,5 GHz</td>
<td>3V/m</td>
<td>$d = \frac{3.5}{3} \times \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = \frac{3.5}{3} \times \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800 MHz to 2,5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>d = ( \frac{3.5}{3} \times \sqrt{P} )</td>
<td>0.12</td>
</tr>
<tr>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

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: Labels

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

Package label

Instructions for use of the device are supplied in electronic form
Les instructions d’emploi du dispositif sont fournies sous forme électronique

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)
Appendix D: 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)).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Low value</th>
<th>High Value</th>
<th>Variability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (HR)</td>
<td>bpm</td>
<td>30</td>
<td>215</td>
<td>1%</td>
</tr>
<tr>
<td>Stroke Volume (SV)</td>
<td>mL</td>
<td>0</td>
<td>220</td>
<td>5%</td>
</tr>
<tr>
<td>Stroke Volume Index (SVi)</td>
<td>mL/m²</td>
<td>0</td>
<td>100</td>
<td>5%</td>
</tr>
<tr>
<td>Cardiac Output (CO)</td>
<td>L/min</td>
<td>0</td>
<td>40</td>
<td>5%</td>
</tr>
<tr>
<td>Cardiac Index (CI)</td>
<td>L/min/m²</td>
<td>0</td>
<td>20</td>
<td>5%</td>
</tr>
<tr>
<td>Contractility Index (CTI)</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventricular Ejection Time (VET)</td>
<td>ms</td>
<td>117</td>
<td>499</td>
<td>5%</td>
</tr>
<tr>
<td>Ejection Fraction (EF)</td>
<td>%</td>
<td>10</td>
<td>92</td>
<td>5%</td>
</tr>
<tr>
<td>End Diastolic Volume (EDV)</td>
<td>mL</td>
<td>0</td>
<td>300</td>
<td>5%</td>
</tr>
<tr>
<td>Systemic Vascular Resistance index (SVRI)</td>
<td>Dyn.s/cm².m²</td>
<td>0</td>
<td>6000</td>
<td>Refer to Blood pressure user manual</td>
</tr>
<tr>
<td>Systemic Vascular Resistance (SVR)</td>
<td>Dyn.s/cm⁵</td>
<td>0</td>
<td>3000</td>
<td></td>
</tr>
<tr>
<td>Systolic Arterial Pressure (SAP)</td>
<td>mmHg</td>
<td>20</td>
<td>330</td>
<td></td>
</tr>
<tr>
<td>Diastolic Arterial Pressure (DAP)</td>
<td>mmHg</td>
<td>20</td>
<td>330</td>
<td></td>
</tr>
<tr>
<td>Mean Arterial Pressure (MAP)</td>
<td>mmHg</td>
<td>20</td>
<td>330</td>
<td></td>
</tr>
<tr>
<td>Left Cardiac Work index (LCWi)</td>
<td>kg.m/m²</td>
<td>0</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Early Diastolic Filling Ratio (EDFR)</td>
<td>%</td>
<td>8</td>
<td>285</td>
<td>5%</td>
</tr>
<tr>
<td>Thoracic Fluid Index (TFi)</td>
<td>Ohm</td>
<td>15</td>
<td>60</td>
<td>5%</td>
</tr>
<tr>
<td>Thoracic Fluid Content (TFC)</td>
<td>/kOhm</td>
<td>16</td>
<td>66</td>
<td>5%</td>
</tr>
<tr>
<td>Thoracic Fluid Content index (TFCi)</td>
<td>/kOhm/m²</td>
<td>8</td>
<td>33</td>
<td>5%</td>
</tr>
</tbody>
</table>

² 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.