

PHYSIOFLOW[®] Lab1™

Service Manual

Monday 10 July 2017

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| First placing on the market: 7 th April 1999 |
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Service Manual PhysioFlow[®] Lab1™

1. General Information

About this manual

This manual contains all the required information for installation, use, maintenance, transport and storage operations for the PhysioFlow[®] Lab1 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

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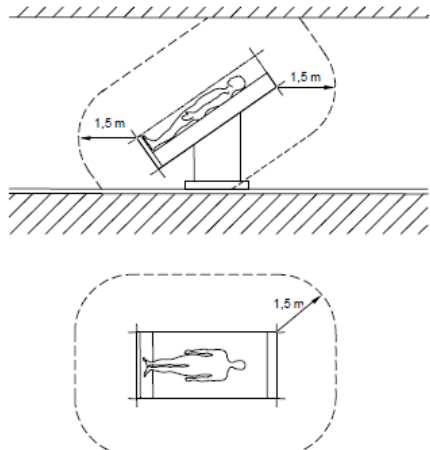
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Technical support
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Definitions

| | |
|---------------------|---|
| Patient Environment | <p>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).</p>  <p style="text-align: right;"><small>IEC 2431/06</small></p> |
|---------------------|---|

Conditions of Use

The PhysioFlow[®] Lab1 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).

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|  | <p><i>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).</i></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.

Functions

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

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 xiphoid 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. 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

| | |
|--|--|
| | <ul style="list-style-type: none"> ○ The device is used in accordance with the operating instructions. ▪ Any modification of any electro medical PhysioFlow[®] device is forbidden. ▪ 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. ▪ PhysioFlow[®] devices must not be sterilized. ▪ FOR ACCURATE MEASUREMENTS, IT IS ESSENTIAL THAT THE OPERATOR UNDERSTANDS THE DIFFERENCE BETWEEN ACCEPTABLE SIGNAL AND POOR SIGNAL QUALITY. (cf. PhysioFlow[®] Software manual, or third party monitor manual). |
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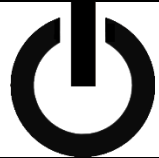

Precautions

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

| Symbol | Signification |
|---|--|
|  | <p>In the manual: Important information to consider for an efficient and optimized use of the system.</p> <p>On the device panel: Led indicator to mention that an error has been detected. If the LED is on please contact PhysioFlow[®] support platform (support@physioflow.com)</p> |
|  | 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. |
|  | PhysioFlow [®] power light: When the LED is on then the device is correctly powered. |
|  | Connections linked to the patient are BF Type. |
| 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. |

2. Overall presentation



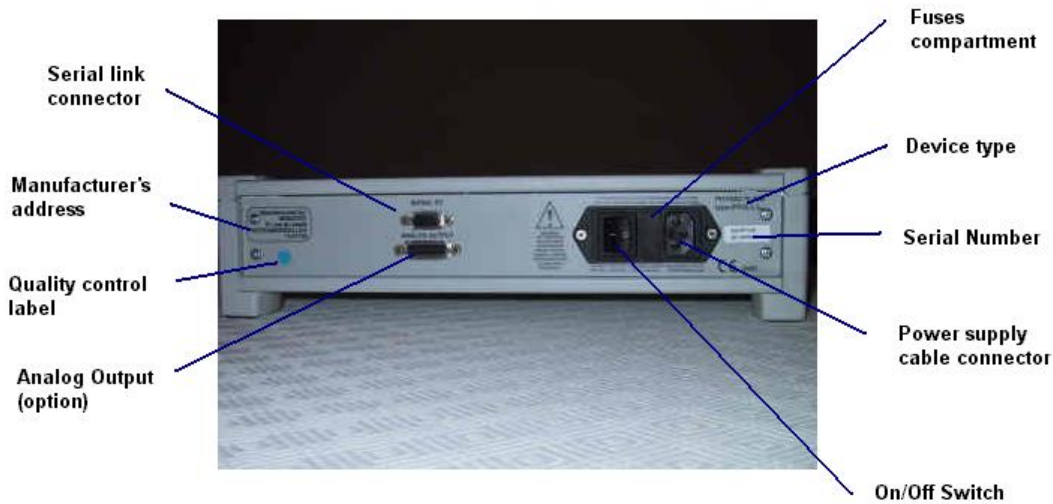
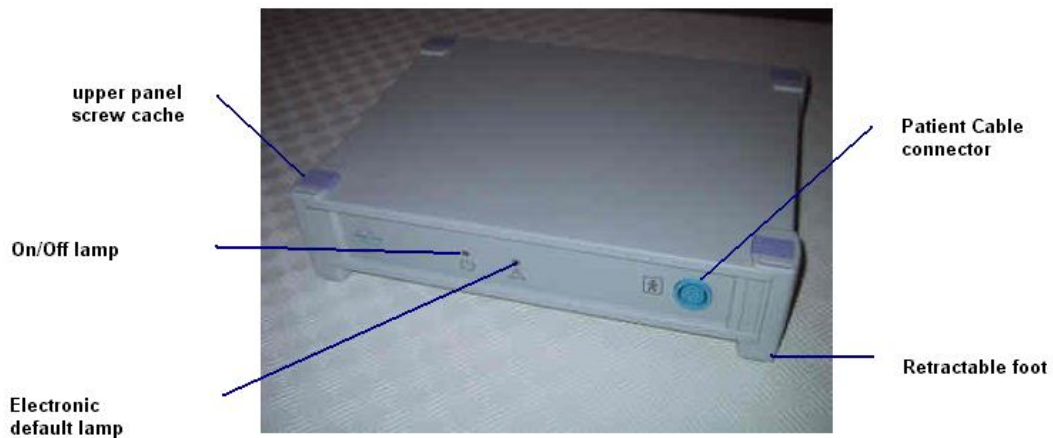
PhysioFlow[®] is a non-invasive cardiac output monitor. It consists in an electronic device, connected to a PC compatible computer through a RS 232 C serial link. It is based on the principles of impedance cardiography.

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

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

3. Interfaces

Description of the electronic unit



Description of cables

A) Electrical RS-232 serial link cable (to be used with a laptop computer only)

Type zero modem, with SUB-D9 Male/Female connectors (fully EMI shielded)



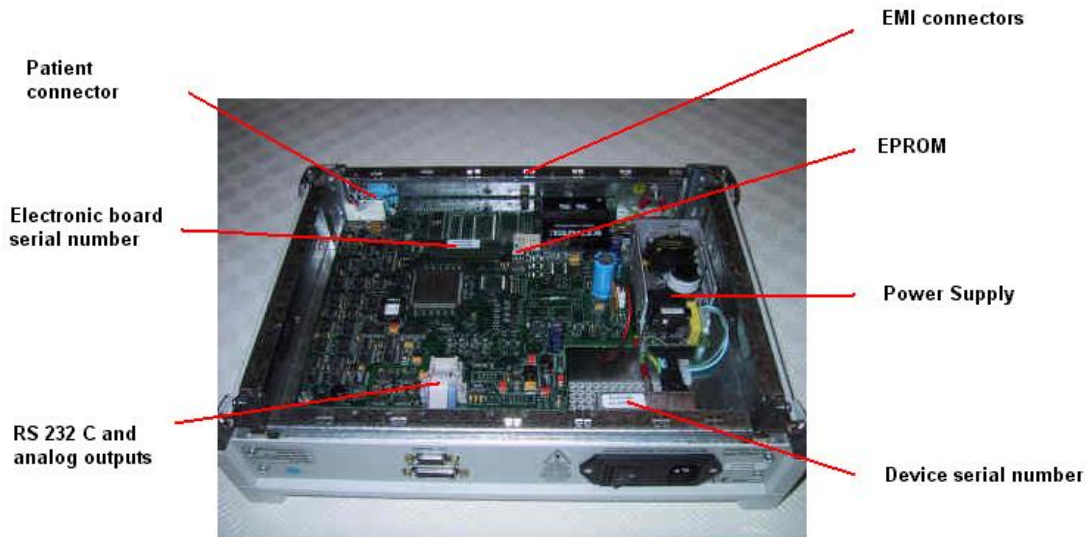
B) Special optical RS-232 serial link cable (compulsory for use of PhysioFlow with a desktop computer)



C) Patient cable



Description of the inside of the unit



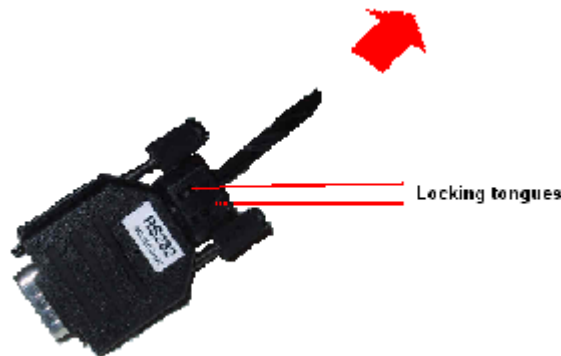
4. Instructions, Problems

Troubleshooting

The orange lamp is permanently on or flashes during measurement: please call your « after sales service » for instructions (customer support +33 3 72 82 50 00 or support@physioflow.com, or your local dealer)

The device does not switch on: please check fuses on back panel, and replace them if necessary. If problem remains, then call your « after sales service » for instructions (customer support +33 3 72 82 50 00 or support@physioflow.com, or your local dealer)

No ECG and no impedance signal are displayed: verify that the patient cable is connected on PhysioFlow[®] and that the serial connection is OK. Replace electric RS 232 serial link cable if the problem remains. If you use an optical cable, check if the optical wire is properly plugged into the optical modules. You can as well unplug the wire on both sides, (by pulling the locking tongues on both sides of the mode, and then pulling the wire out of the module). Then use a sharp cutter, and make a neat cut at the wire extremity. Plug the wire in the module again.



No ECG is displayed but other signals are visible: verify the quality of electrodes and their position. Electrodes must not be dry (use a bag that has been opened for less than one month).

ECG and Z signals are inverted: launch again the calibration or acquisition phase in progress.

Analog output pin connection and instructions

SUB-D 15 female connector on back panel.

Pin15 : Z
Pin 8 : Gnd
Pin13 : Stroke Volume
Pin 6 : Gnd
Pin11 : ECG
Pin 4 : Gnd
Pin9 : CO
Pin 2 : Gnd

The 4 outputs are -2.5V to +0.0V full scale / 10Kohms output impedance.

Please connect PhysioFlow[®] to a medical system compliant with CE regulations or with your local medical regulations.

The Stroke Volume and Cardiac Output trends only operate when calibration phase is completed on the computer. The external data acquisition system has to be calibrated (adjustment of scales) to reproduce measurements displayed on the PhysioFlow[®] Computer screen.

To perform this task, start a measurement on a volunteer who is very relaxed and stable. Please calibrate SV and CO measurement on your acquisition system in accordance with the readings you obtain on the PhysioFlow[®] screen. Then make a change (for instance by retrieving the white electrode), and calibrate again your system in accordance with the new PhysioFlow[®] readings obtained.



When using PhysioFlow[®] Software 2.0.0 and later, only the Z (Pin15) and ECG (Pin11) outputs are active. In this case, it not possible yet to get neither CO on Pin9 nor SV on Pin13.

This feature is planned for a future software version. If you need it, please contact the technical support: support@physioflow.com.

5. Maintenance, Transport, Storage and Disposal

Service and maintenance

There is no operator or customer serviceable part, and no part has to be changed under normal tear and wear conditions.

If the system does not work properly, please refer to the troubleshooting section. If the problem remains, please contact your authorised dealer, or the customer support +33 3 72 82 50 00 or support@physioflow.com.

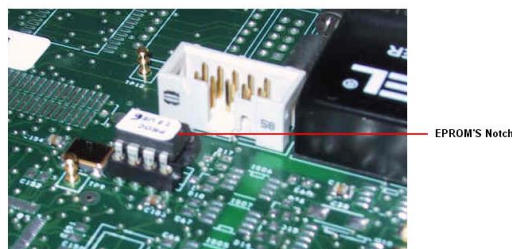
With special authorisation of the manufacturer or the dealer, the unit's embedded processor software can be upgraded. To perform this operation, it is necessary to replace the EPROM.

First stage is to open the enclosure. To do that, please slide the 4 caches on the upper side of the device, and unscrew.



Replacing the EPROM requires pliers, protected against static electricity. The EPROM must be retrieved very slowly and carefully from the support, by gripping the edges of the EPROM. Be careful, the new EPROM has to be put in place very carefully.

IT IS INDISPENSABLE THAT THE NEW EPROM IS POSITIONED THE SAME WAY THAN THE PREVIOUS ONE: THE NOTCH ON THE UPPER SURFACE MUST BE DIRECTED TOWARDS THE POWER SUPPLY (SAME DIRECTION AS THE PHYSIOFLOW[®] LOGO ON THE FRONT PANEL AND OPPOSITE TO THE PATIENT CONNECTOR).



Storage and cleaning

Out of operation periods, the PhysioFlow[®] unit must be stored at ambient temperature (between -40°C and +70°C, humidity included between 10% and 100%, and an atmospheric pressure included between 500 hPa and 1060 hPa).

The device and its accessories must be cleaned with a clean and dry or slightly wet cloth. **Don't plug the PhysioFlow[®] on the electrical network during the cleaning operation.**

Appendix A: Legislation

Computer must comply with regulations concerning medical devices (Desktop computer, or laptop with leakage current under 0.1 mA). Please refer to the manufacturer information.

Please connect PhysioFlow[®] to a CE marked device, compliant with medical norms.

LEGISLATION:

CE marking in accordance with EC directive 93/42/CEE concerning medical devices (class II A).
Device approved by the Japanese Ministry of Health.

Appendix B: Specifications

| General | |
|--|--|
| Dimension | 343 x 260 x 84 mm |
| Weight | 4.0 Kg |
| Protection | Full EMI protection, (Metallic enclosure with special EMC shielding) |
| Power supply | 100-240 VAC 50/60 Hz |
| Fuses | 1A/250V only |
| Power input | 50 VA |
| Galvanic insulation of patient, and optical coupling | Device of BF type |
| Electrodes | 6 Ag/AgCl pregelled adhesive electrodes per examination Recommended : Agilent HP40493E |
| Connectors | |
| Back panel | Female SUB-D9 (serial link to PC) Switcher-filter-fuses module Schaffner |
| Front panel | Specific patient connector (6 leads + ground) Gilded contacts |
| Measurement current | Intensity of 3.6 mA peak to peak Sinus frequency : 75 KHz |
| Operating temperature | 5°C - 55°C |
| Patient cable | 6 leads, EMCD shielded Length 3.5 meters (ref. SP090) or 10 meters (ref SP090-10M) Gilded contacts |
| Specific RS232 serial link | Null modem type wiring (1,8 Meters) SUB-D9M/SUBD9F connectors Optical cable available, (for connection with a desktop computer). |
| Power supply cable | 2P+T/CEE 22 (computer type) (3 meters) |
| Computer environment | |
| Minimal computer configuration | PC Pentium compatible Desktop or Laptop 200 MHz, 32Mb RAM, HD 50 Mb free, screen 800x600, 65536 colours Microsoft Windows 95 / 98 / Me / NT / 2000 operating system. 1 available serial link (RS 232) |

Appendix C: Physiological parameters

This table provides the list of parameters provided by the PhysioFlow[®] PF-05 Lab1 system.

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) ¹ | mmHg | 20 | 330 | |
| Diastolic Arterial Pressure (DAP) ¹ | mmHg | 20 | 330 | |
| Mean Arterial Pressure (MAP) ¹ | mmHg | 20 | 330 | |
| Left Cardiac Work index (LCWi) | kg.m/m ² | 0 | 30 | |
| Early Diastolic Filling Ratio (EDFR) | % | 8 | 285 | 5% |

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