

510(k) Summary K060387

APR 10 2008

Submitter

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Contact Name: Jim Gunnerson

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Date this Summary was Prepared: April 4th 2008

Trade Name

PhysioFlow

Common Name

Noninvasive Hemodynamic Monitor

Classification Name

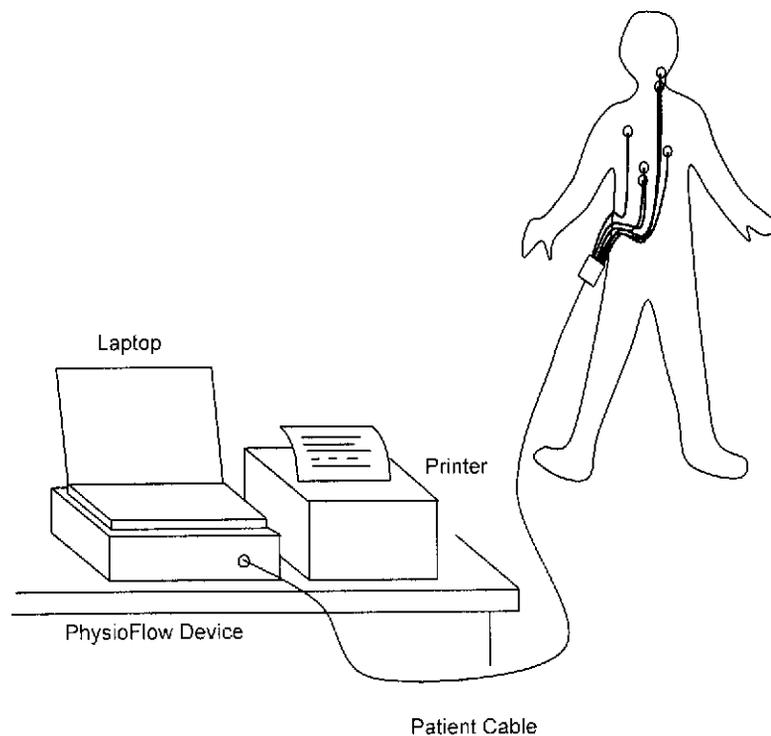
Impedance plethysmograph (per 21 CFR 870.2770)

Predicate Device

Philips ICG
(Formerly Analogic Corp.)

510(k) number K041434

Device Description



The PhysioFlow System is a noninvasive hemodynamic monitor that uses thoracic electrical bioimpedance technology to measure cardiac output and related parameters.

It has three main components :

1. An electronic device that generates a low magnitude, high frequency electrical current (the "impedance current"), sends it through the body of the patient via a patient cable and pre-gelled electrodes (the sensors), and receives it after it has crossed the patient thorax. The impedance modulation (ΔZ) is extracted from the received signal, providing a pulsatile waveform used by the software to compute stroke volume. The device also records one lead of a passive electrical signal that is similar to the ECG, in order to provide a time basis and trigger for the analysis of the impedance waveform, and to provide a measurement of heart rate. This ECG signal is not used for electrocardiography analysis. The device filters and digitizes both the impedance and the ECG signals, and transmits them to a computer via a serial communications link. The device has an analog output option, which makes the following signals available : ΔZ , ECG, Cardiac Output trend, and Stroke Volume trend.
2. A computer that runs a MS-Windows operating system, and performs the following tasks :
 - Reception of digitized signal samples from the device via a serial port
 - Platform to operate the PhysioFlow software
 - Physical user interface (keyboard, mouse, display)
 - Patient data storage capacity (on hard disk)

- (Optional) Reception of blood pressure values from an external blood pressure monitor device via a serial port (This device does not measure blood pressure)
- Management of a printer using the appropriate driver

3. The PhysioFlow software, which performs following tasks :

- Signal processing and analysis
- Computation of measured parameters
- User interface and control of the measurement process (entering patient data, calibration procedure, monitoring phase, post processing of measurement results)
- Transmitting cardiac output and stroke volume values back to the device via a serial data link for analog output purposes
- Management of event markers
- Setup of measurement and screen configuration (averaging ratio, scales, screen appearance, printout options)
- Display of signal, trends, and graphics
- Management of imported data (blood pressure values from external monitor)
- Management of patient data
- Export of measurement data in text format (for import into programs such as Excel)
- Generating hard copy output

The PhysioFlow System was designed and developed by Manatec Biomedical, a French company with headquarters in Petit-Ebersviller, France. The PhysioFlow System has been CE marked according to the European Medical Device Directive (93/42/CEE) as a class IIa device, and has been certified by the Japanese Ministry of Health and Health Canada. The PhysioFlow System is manufactured in France according to the ISO 13485 and ISO 9001 standards.

Intended Use

The PhysioFlow System noninvasively measures cardiac output and other related cardiac parameters on adults. These parameters include:

CI	Cardiac Index
CO	Cardiac Output
CTI	Contractility Index
EDV	End Diastolic Volume
EF	Ejection Fraction
HR	Heart Rate
LCWI	Left Cardiac Work Index
PEP	Pre Ejection Period
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
TFI	Thoracic Fluid Index
LVET	Left Ventricular Ejection Time

The PhysioFlow System is intended for use under the direct supervision of a licensed healthcare practitioner or personnel trained in its proper use within a hospital or facility providing healthcare.

Technological Characteristics Compared to Predicate Device

The PhysioFlow System and the Philips ICG System both have the same general intended use. Both systems provide means for making noninvasive measurements of cardiac output and related cardiac parameters.

Both the PhysioFlow System and the Philips ICG System utilize the same basic technology, i.e., the measurement of thoracic electrical bioimpedance. The low current, high frequency electrical signals used in both systems to measure impedance are very similar.

The procedure for taking the measurements is similar for both systems. The connection from the measurement device to the patient in both systems includes a multi-lead patient cable that attaches to a number of disposable, pre-gelled, Ag/AgCl electrodes, which are applied to the patient's neck and thorax for a short period of time.

Both systems have similar features such as a keyboard or data entry interface for typing in relevant patient data (such as name, height, and weight), a display for showing the ECG and impedance signals in real time, the ability to display the computed cardiac parameters numerically and graphically, the ability to store records of a patient measurement session, and the ability to print hard copy reports.

Both systems handle noninvasive blood pressure (NIBP) readings by importing measurements from connected FDA-cleared devices. The PhysioFlow system also provides the ability for blood pressure values to be entered manually as an alternative. Both systems provide connections for analogue output of signals to other medical devices.

The differences between the PhysioFlow System and the Philips ICG System are minor. The PhysioFlow System software runs on Windows, whereas the Philips ICG software runs on its own operating system. The mechanical packaging differs in that the PhysioFlow System device connects to a suitable computer via an external serial cable connection, while the Philips ICG System device was built into a box that also enclosed the CPU.

The parameters and signals that are monitored, calculated and/or reported by the two units are compared in the tables below. They are essentially identical except for the Contractility Index which is similar to the Acceleration Index parameter reported on the PHILIPS ICG device.

Table 1 – Signal Comparison

Signal	Description	PHILIPS ICG	PhysioFlow
ECG	Electrocardiogram (for triggering purposes only)	X	X
Z	Impedance	X	X
dECG / dT	First derivative of electrocardiogram		X
dZ / dT	First derivative of impedance	X	X
d ² Z / dT ²	Second derivative of impedance		X

Table 2 – Parameter Comparison

Parameter	Description	Units	PHILIPS ICG	PhysioFlow
ABP	Arterial Blood Pressure	mmHg	X	X
ACI	Acceleration index	1/sec.sq	X	
BSA	Body Surface Area	m ²	X	X
CI	Cardiac Index	l / min / m ²	X	X
CO	Cardiac Output	l / min	X	X
CTI	Contractility Index	no unit		X
CVP	Central Venous Pressure	mmHg		X
DAP	Diastolic Arterial blood Pressure	mmHg	X	X
EDV	End Diastolic Volume	ml		X
EF	Ejection Fraction	%		X
Height	Height	cm	X	X
HR	Heart Rate	bpm	X	X
LCWI	Left Cardiac Work Index	kg.m / m ²	X	X
LVET	Left Ventricular Ejection Time	millisec	X	X
MAP	Mean Arterial blood Pressure	mmHg	X	X
PEP	Pre Ejection Period	sec	X	X
SAP	Systolic Arterial blood Pressure	mmHg	X	X
STR	Systolic Time Ratio	No unit	X	
SV	Stroke Volume	ml	X	X
SVI	Stroke Volume Index	ml / m ²	X	X
SVR	Systemic Vascular Resistance	dyn.s.cm ⁻⁵	X	X
SVRI	Systemic Vascular Resistance Index	dyn.s.cm ⁻⁵ .m ²	X	X
TFI/TFC	Thoracic Fluid Index/Content	no unit	X	X
VI	Velocity Index	1/sec/ cm ²	X	
Weight	Weight	kg	X	X

Conclusions

Vasocom has provided bench and clinical data to verify that the subject device can indeed record cardiac output similar to the predicate device. The clinical study data includes 84 subjects at two centers, and compared the PhysioFlow Device to the predicate device and also to the Swan-Ganz catheter using thermodilution.

Based on technological comparisons and performance testing results, in its overall intended use, functioning, safety and efficacy, the PhysioFlow System is substantially equivalent to the Philips ICG System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2008

VasoCOM, Inc.
c/o Mr. John S. Samorajczyk
Samorajczyk Regulatory Consultants, LLC
5414 Leilani Drive
St. Pete Beach, FL 33706

Re: K060387
Trade/Device Name: PhysioFlow System, Model PF05
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (Two)
Product Code: DSB
Dated: February 5, 2008
Received: February 5, 2008

Dear Mr. Samorajczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

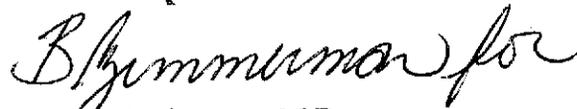
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Mr. John S. Samorajczyk

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K060387

Device Name: PhysioFlow System

Indications for Use:

Indicated for use in adults only

The PhysioFlow System noninvasively measures cardiac output and other related cardiac parameters. These parameters include:

CI	Cardiac Index
CO	Cardiac Output
CTI	Contractility Index
dZ / dT_{max}	Maximum value dZ / dT
EDV	End Diastolic Volume
EF	Ejection Fraction
HR	Heart Rate
LCWI	Left Cardiac Work Index
PEP	Pre Ejection Period
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
TFI	Thoracic Fluid Index
VET	Ventricular Ejection Time
Z_0	Base Impedance

K060387

The PhysioFlow System is intended for use under the direct supervision of a licensed healthcare practitioner or personnel trained in its proper use within a hospital or facility providing healthcare.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Bimmuno
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060387