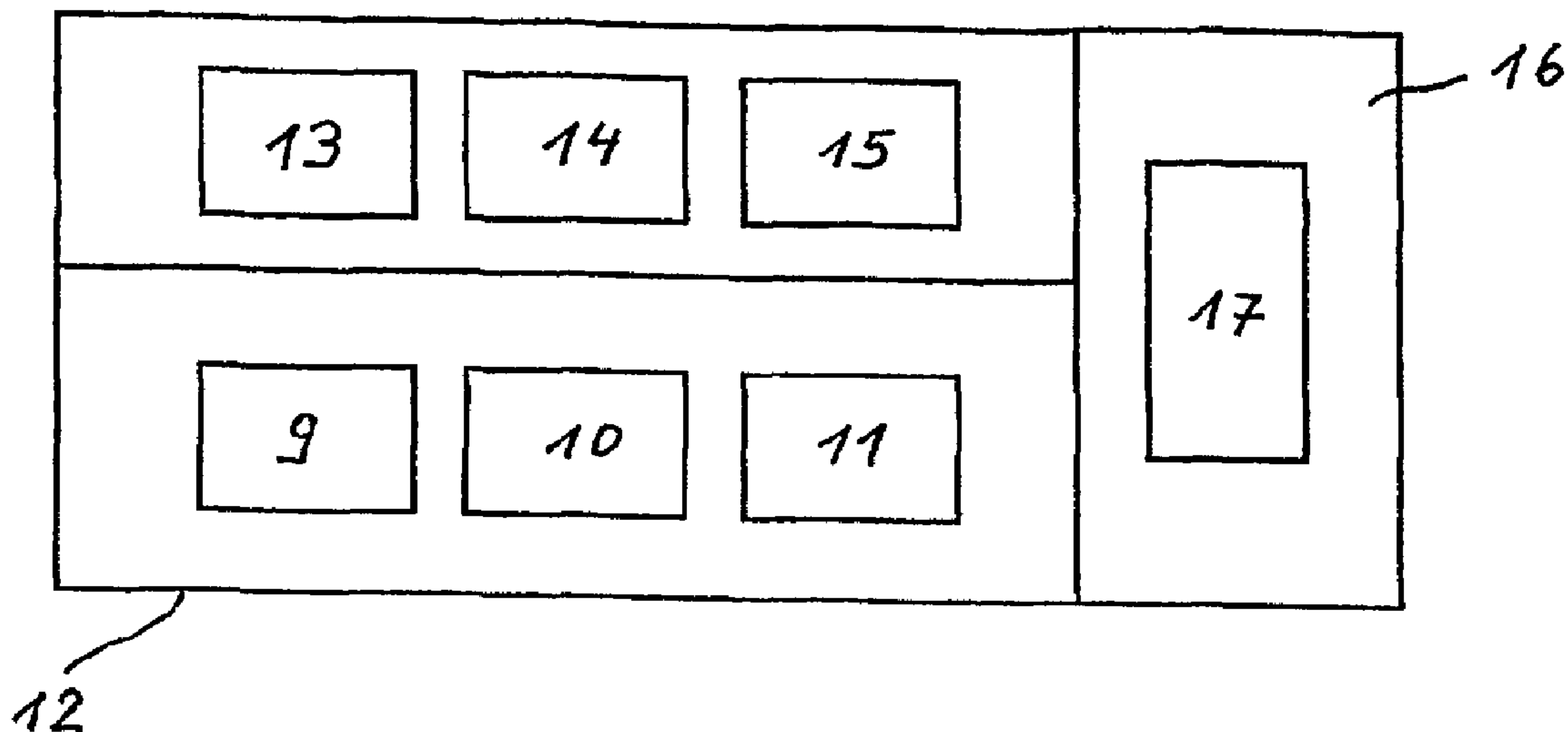




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(57) Abrégé/Abstract:

The invention relates to a device for muscle stimulation, said device comprising a pulse generator unit (9) for producing and sending an electrical stimulation pulse; a control unit (10) for controlling the pulse generator unit (9) in order to adjust the amplitude and the frequency of the stimulation pulses and to cause the transmission of stimulation pulses to a muscle to be stimulated; a detection unit (11) for detecting the instantaneous, spontaneous or stimulated cardiac rhythm of the carrier of the device; a housing (12) receiving the pulse generator unit (9), the control unit (10), and the detection unit (11); a counting unit (13) and a memory unit (14) for counting and storing the number of stimulation pulses emitted within a definable time interval; and a determination unit (15) for determining the arithmetic average of the stimulation frequency within the definable time interval.

ABSTRACT

The invention relates to a device for muscle stimulation, said device comprising a pulse generator unit (9) for producing and sending an electrical stimulation pulse; a control unit (10) for controlling the pulse generator unit (9) in order to adjust the amplitude and the frequency of the stimulation pulses and to cause the transmission of stimulation pulses to a muscle to be stimulated; a detection unit (11) for detecting the instantaneous, spontaneous or stimulated cardiac rhythm of the carrier of the device; a housing (12) receiving the pulse generator unit (9), the control unit (10), and the detection unit (11); a counting unit (13) and a memory unit (14) for counting and storing the number of stimulation pulses emitted within a definable time interval; and a determination unit (15) for determining the arithmetic average of the stimulation frequency within the definable time interval.

Device for muscle stimulation

The invention concerns a device for muscle stimulation having the features of patent claim 1.

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Muscularly driven heart support systems (e.g. cardio-myoplasty, aorto-myoplasty, musculoskeletal ventricle, biomechanical hearts) are applied already partly clinically, partly still experimentally as supplementary to or replacement therapy of heart transplants and as treatment of a terminal cardiac insufficiency. In this
10 conjunction these muscular support systems can operate parallel to as well as in series with the diseased heart. On the one hand they serve for its relief (reduction of the cardiac wall tension, pressure relief, volume reduction, lowering of the afterload) and on the other to support the blood circulation, i.e. to increase the mean pressure of the arterial blood pressure and/or to increase the pumped
15 volume. Independently from the configuration of the heart support system for, the targeted stimulation of a muscle contraction a muscle pacemaker is required, that by means of stimulation electrodes emits synchronously with the heart an electric stimulation pattern to the muscle to be supported. On this occasion a stimulation pattern comprises a sum of individual pulses, which can be described by their
20 stimulation tension, the pulse width and the interval between two pulses. By a sensible combination of a plurality of individual pulses into a group of individual pulses with a subsequent intermission a stimulation burst will occur, that is used for the cyclical contraction and relaxation of the muscle tissue. To describe a stimulation pattern, in addition to the aforementioned parameters the number of
25 stimulation pulses per burst and the frequency of application of a stimulation burst is to be taken into consideration. A further parameter is the positioning of the stimulation burst within the heart cycle, that is defined by a delay period.

Experiments on large animals have shown, that a long-lasting and frequent
30 application of the stimulation bursts leads to a transformation of the fibres of the stimulated musculature, whereby although the emerging muscle fibres are fatigue-free to a great extent, they are weak and slow. It could be observed, that in the case of a long-lasting and frequent application of stimulation bursts the cross-section of the muscle fibres have been considerably reduced. This

musculature, determined mainly by Type-I muscle fibres, is only moderately suited to accomplish a circulation-effective pumping work. Experimental investigations have, however, shown, that before the transformation of the stimulated muscle fibres into Type-I muscle fibres an intermediate form of the transformation into an already fatigue-free, but still strong Type-IIa muscle fibres can be achieved. This fast and simultaneously strong musculature, dominated by Type-IIa muscle fibres, is, however, retained only when the number of the stimulation pulses applied per unit of time remains below an upper limit value. A stimulation above this upper limit unavoidably leads to the transformation of the Type-IIa muscle fibres into Type-I muscle fibres, accompanied by a loss of muscle power and speed.

Existing muscle-pacemaker systems are in the position to emit pre-defined and calculated stimulation bursts synchronously with and triggered by the heart rhythm in an adjustable ratio of muscle contraction to heart contraction. This ratio can be pre-defined depending on the heart rate. If there is, for example, a high heart rate over a longer period, then the muscle pacemaker will also emit always the same and high number of stimulation pulses. This will lead to an excessively frequent use of the muscular heart support system with the consequence of a further transformation of the muscle fibres into weak and slow Type-I muscle fibres. Consequently, muscularly driven heart support systems lose their support potential, due to which the diseased heart no longer can be effectively relieved. With further usage the circulation support deteriorates, due to which, as a compensation, the heart rate of the patient can further increase. This may result in a complete degeneration of the supported muscle.

DE 101 52 741 A1 discloses a heart therapy equipment, in particular as an implantable defibrillator, heart pacemaker or combined heart pacemaker/defibrillator, with an evaluating and control device to evaluate a measured heart rate, which has a tri-region memory to store a first, second and third value range of comparison heart rates that border the heart rate with increasing values, a heart rate discriminator to assign a measured heart rate to the first, second and third value range and a stability evaluating device to evaluate the heart rate stability over a predetermined period of time while

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establishing a heart rate situated in the second value range. When a heart rate is recorded in the second value range, one of two different therapy control signals is emitted, in fact depending on the stability of the heart rate. The criterion of stability serves the purpose of distinguishing between "fast" tachycardia ("flutter") and fibrillations with, still, relatively low frequency. The subject matter of US 4 406 287 is also a pacemaker. A tachycardia is supposed to be terminated with this device, while various pulse numbers/pulse rates may be used. Should a tachycardia not end after the application of a first combination of a pulse number and a pulse rate, a phase with a second modified combination of a pulse number and a pulse rate will follow. Following this the last successful combination of the pulse number and pulse rate is stored and is used as commencing value for the next termination of the tachycardia. The probability of the termination of a tachycardia is to be increased in this manner.

US 2003/0 083 703 A1 discloses a method and an arrangement to provide an anti-tachycardia pulse pattern. It is also possible to determine with this device, whether a pulse pattern has terminated the tachycardia and whether a modification of the pulse muster is appropriate.

Based on this, the object of the invention is to provide a muscle stimulator, that makes it possible to obtain Type-IIa muscle fibres, so that to provide a particularly efficient muscular heart support system acting on demand. Furthermore, the muscle stimulator should be able to induce a regeneration of vessels and capillaries for the optimum blood supply of the musculature (neovascularisation) by suitable electric stimulation.

According to one aspect of the present invention, there is provided a device to induce muscle contractions of a muscularly driven heart support system, that operates parallel to or in series with a diseased heart, comprising: a pulse generating unit to produce and emit an electrical stimulation pulse; a control unit to control the pulse generating unit to adjust the amplitude and frequency of the stimulation pulse and to ensure that the stimulation pulses are delivered to a muscle to be stimulated; a detection unit to detect the momentary, spontaneous or stimulated heart rhythm of the bearer of the device; a housing, in which the pulse generator unit, the control unit and the detection unit are accommodated; a

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memory module to store the temporal progress of the number of stimulation pulses delivered within a definable period of time, as well as a counting unit and a memory unit to count and store the number of stimulation pulses delivered within a definable period are provided, while the stimulation pulses are grouped into

5 modifiable stimulation bursts, wherein a determination unit to determine an arithmetically averaged (average) stimulation frequency within the definable period of time, while the average stimulation frequency is the quotient of the stimulation pulses of the modifiable stimulation bursts stored by the memory unit and delivered within the defined period of time and of the defined period of time, in

10 which the stimulation pulses were counted and stored, wherein a continuously operating evaluation unit is provided to adhere to the limit values for the average stimulation frequency, wherein pulse saving means are provided to reduce the average stimulation frequency depending on the maximum average stimulation frequency determined by the evaluation unit, wherein the pulse saving means

15 comprise a calculating unit to calculate a stimulation pattern according to an equation, that determines the stimulation pattern depending on the average stimulation frequency, while the number of stimulation pulses per stimulation burst is variable to reduce the average stimulation frequency, wherein a monitoring unit, carried extracorporeally by the patient, is provided to illustrate the average

20 stimulation frequency and for self-control of the patient, and wherein the limit values for the average stimulation frequency are individually adjustable in a range of 0.2 stimulation pulses/sec up to 2 stimulation pulses/sec.

In some embodiments, a muscle stimulator is provided, comprising a pulse generating unit to produce and emit an electrical stimulation pulse, as well as a

25 control unit to control the pulse generating unit. The amplitude, i.e. the stimulation voltage, the frequency, the temporal distribution of the stimulation pulse, the type and frequency of the support modes and the delay period to the R-wave, the day/night rhythm as well as the position of the phase of the stimulation pulse can be adjusted via the control unit. The stimulation pulse is conveyed from the control

30 unit via conducting means to one or several muscles to be stimulated.

Furthermore, the muscle stimulator according to the invention has a detection unit to detect the momentary spontaneous or stimulated heart rhythm of the bearer of the muscle stimulator. The detection unit serves the purpose of detecting the

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R-wave, that as basis serves for the triggering of the stimulation pulse and the calculation of the temporal delay between the R-wave of the heart rhythm and the stimulation burst. The pulse generator unit, the control unit and the detection unit are accommodated in a common housing, that can be extracorporeally carried or
5 can be implanted in the body of the patient.

A counting unit and a memory unit are provided to count and to store the number of stimulation pulses delivered within a definable period. Furthermore, a determination unit is provided to determine an average stimulation frequency within the definable period.

- 10 The average stimulation frequency is the quotient of the stimulation pulses stored by the memory unit and delivered within a defined period of time and of the defined period of time, in which the stimulation pulses were counted and stored (detection period/observation period). Therefore one deals with an arithmetically averaged stimulation frequency, while in the following the term average
15 stimulation frequency is used to represent the arithmetically averaged stimulation frequency.

The counting unit and/or the memory unit and/or the determination unit are not necessarily accommodated within the aforementioned housing, that can be accommodated in a separate housing, in particular in an extracorporeally carried
20 housing.

To prevent an excessive stimulation of the stimulated muscle and thus an undesirable transformation of the stimulated muscle fibres into a weak, slow and consequently ineffective Type-I musculature, it is necessary to count the stimulation pulses delivered within a definable period of time and convey them to an evaluation. This task is assumed by the counting unit in conjunction with the memory unit and a monitoring unit. The average stimulation frequency is a measure of the frequency of stimulation of the muscle in a certain period of time. To avoid damaging the muscle, this average stimulation frequency must not exceed on the long term a limit value that is to be individually determined.

10

Each emitted stimulation pulse is counted and calculated over a longer observation period as the average stimulation frequency. In the spirit of the invention a longer observation period means 30 minutes at least, in particular, however, one or several hours. Observation periods are usefully 12 or 24 hours.

15 The average stimulation frequency is to be determined individually for each patient and must not exceed a maximum value of 0.2-2 pulses/sec (Hz), in particular 0.7-1 Hz, so that to prevent a straining of the muscle and a medium-term muscle destruction. It is therefore important to evaluate the average stimulation frequency with regard to the desired muscle transformation and

20 maintenance effect and to control the stimulation pulse delivery depending on the result of the evaluation. For this purpose a continuously operating evaluation unit is provided to adhere to the limit values for the average stimulation frequency, while the limit values can be individually adjusted in a range of 0.2 stimulation pulse/sec up to 2 stimulation pulses/sec. Pulse saving means serve the purpose

25 of adapting, and in particular reducing, the average stimulation frequency depending on the recorded average stimulation frequency and the predetermined nominal values of the evaluation unit. The pulse saving means comprise a calculating unit to calculate a modified stimulation pattern according to an equation, that depends on the average stimulation frequency. Furthermore, a

30 memory module may be provided to store the temporal progress of the number of stimulation pulses delivered, as well as a means for the program-controlled transmission of the average stimulation frequency from the determination unit to the calculating unit. Furthermore, an analysis unit may be provided to determine

as to when and how often established limit values of the heart rate and/or of the average stimulation frequency were exceeded or not reached.

5 As far as spatial arrangement is concerned, the counting unit and the memory unit can be accommodated in one housing. In addition, the determination unit and/or the pulse saving means can also be integrated in the housing. The memory module and/or the analysing unit can also be optionally integrated in the housing, that accommodates the control unit. The housing of the device according to the invention can be implanted into the body of the bearer. An
10 energy storage is additionally allocated to the housing, said energy storage being able to be transcutaneously charged. By virtue of this the service life of the implanted part of the device will be prolonged.

It is, of course, also feasible within the scope of the invention, that the counting
15 unit and/or the memory unit and/or the determination unit and/or the pulse saving means and/or the memory module and/or the analysing unit are components of a monitoring unit that is stationary and/or is carried extracorporeally by the bearer. The average stimulation frequency and/or a magnitude range, into which the average stimulation frequency falls, can be illustrated on this monitoring unit
20 optically and/or acoustically and/or in a tactile manner via indicating means. The monitoring unit has optionally a programming device to produce a programming signal and a transfer device to transfer the programming signal to a transmission and reception unit in the housing, accommodating the control unit. In the monitoring unit additional means may be provided to transmit and receive
25 positional data. The monitoring unit comprises optionally means to transmit and receive wireless signals to transmit physiological data of the patient to a display and evaluating unit of a receiver.

A subject matter of the invention is a combination of specially developed
30 electronic equipment to produce and to maintain Type-IIa muscle fibres for muscular heart support systems, in particular for muscular blood pumps. The invention also concerns an external myostimulator, that can be so programmed, that by a percutaneous stimulation less tiring Type-IIa muscle fibres are produced already pre-operatively. On this occasion one can also deal with an arrangement,

comprising an implantable myostimulator and a monitoring unit that effectively brings the muscle with Type-IIa muscle fibres to contraction, prevents the transformation into Type-I muscle fibres and additionally prevents a muscle destruction by strain. The monitoring unit of this implantable myostimulator serves
5 both as programming device and as measuring and recording device. This monitoring unit can transmit information from the myostimulator to the patient or to the treating doctor in a wireless or wired manner. Further functions, like transmission of the patient's ECG, as well as a patient positioning system for emergencies may be accommodated in this equipment. In addition, this
10 equipment is in the position to materialise to a limited extent the aforementioned functions in myostimulators of other manufacturers.

The invention is explained in detail in the following based on schematically illustrated embodiments. They show in:

15

Fig.1 - a schematic illustration showing how the individual physical elements of a device according to the invention are connected to one another,

Fig.2 - an illustration of the functional components of a device for muscle
20 stimulation in a first embodiment,

Fig.3 - the embodiment of Fig.1, modified,

Fig.4 - a further modification of the device for muscle stimulation with additional
25 functional elements.

In the embodiment, shown in Fig.1, two microcontrollers 1, 2 are used as programmable components. They are characterised by a large number of programmable ports, high processing speed at moderate current consumption
30 and flash-memory with in-system-programmability (ISP). Further components of the muscle pacemaker are a 12-bit analogue/digital converter (A/D converter) 3, a 12-bit digital/analogue converter (D/A converter) 4, several operation amplifiers as well as a telemetry unit 5. The current supply is carried out via long-life batteries, preferably lithium-ion batteries.

The digital portion of the muscle pacemaker essentially comprises two logically separated regions, each of them driven by its own microcontroller 1, 2 as programmable components. The first region, controlled by the microcontroller 1, serves the purpose of generation, amplification and distribution of the stimulation pulses S (max. 40 mA) to four muscle electrodes and two cardiac electrodes. The second region, controlled by the microcontroller 2, serves the purpose of monitoring the patient, recording and storing of measured data, e.g. pressure data D , that are processed in a pressure logics 6 and are conveyed to the microcontroller 2 functioning as a measuring unit, as well as for the telemetric communication with the surrounds. Both logical regions are connected with one another via a multi-purpose connector in the form of a serial interface 7. Both microcontrollers 1, 2 are programmed, for example, in the program language "C". In this conjunction they receive different softwares, specific to their functions.

In the following the functions of the aforementioned logically separated regions are explained in detail.

Region 1:

20 Triggering the heart action:

For the suitable positioning of a stimulation pulse within the heart cycle, the microcontroller 1 receives synchronously with each heart action a trigger signal from a filter circuit (R-wave unit) 8, that comprises eight cascading operational amplifiers OPV, wherein the first four OPVs amplify the incoming ECG signal with an amplitude of approx. 1-10 mV to 2-3 V and filter out the interfering frequencies of 50 Hz and 60 Hz, and the further four stages serve the purpose of extracting the R-wave and generating the Schmitt trigger signal. This trigger signal is detected by the microcontroller 1 and determines the time interval to the previous trigger signal. If, when compared with the last ten temporal trigger intervals, there is a regularity, a stable sine rhythm of the heart is assumed and the heart rate is determined from the intervals of the trigger signals R . The arrows, designated by P , are serial high-speed connections.

Support modes

Depending on the heart rate, various ratios of a muscle contraction to the heart contraction are desired. The adjustable range is between 1:1, i.e. each heart action is supported by a muscle action and 1:255, i.e. a muscle contraction is carried out only after 255 heart action. Up to five different support modes can be defined depending on the heart rate.

Day/night rhythm and labour/rest rhythm

For the muscle pacemaker day and night times, as well as independently from it labour and rest times can be defined, in which the muscle pacemaker alternates between pulse patterns of high activity and pulse patterns of low or nil activity. The change between day and night rhythm or labour and rest rhythm can be carried out depending on the time, controlled by events as well as manually via a control device specific to the patient.

Temporal progress of a muscle stimulation

The appearance of a heart trigger signal R and proof of regularity is added up in a counter until a heart rate, to be supported, is achieved. Subsequently a second counter is activated, that allows a certain time to lapse as delay until producing the stimulation pattern (R-wave delay, R-delay).

Temporal progress during a muscle stimulation

Depending on the pre-setting, after the expiry of the R-wave delay time (R-delay) the stimulation pattern is generated pulse-like with the variables: amplitude, pulse width, pulse phase (positive, negative, biphasic) and interim pulse interval, with the aid of the D/A converter 4 and an operational amplifier circuit (OPV) and fed to defined stimulation electrodes.

Quantifying the stimulation pulses

Each emitted stimulation pulse is counted and calculated over a monitored period of, for example, 24 h, as average stimulation frequency. The average stimulation frequency is to be determined individually for each patient and must not exceed a maximum value of approx. 0.2 Hz to 2 Hz, in particular 0.7 to 1 Hz, so that to prevent a strain of the muscle and a medium-term muscle destruction.

Output of the average stimulation frequency

As important and new feed-back mechanism for the bearer of the muscle pacemaker and for the treating doctor, the output of the average stimulation frequency represents a suitable means to early recognise muscular strains, counteract them and thus prevent a potential destruction of the muscle tissue. For this purpose the microcontroller transmits by wireless data transmission, at regular intervals which can be set by the doctor, the average stimulation frequency, that is received by a monitor carried by the patient and is perceivable by the patient, in particular is illustrated in a visible form. Should the average stimulation frequency be in a critical range, the microcontroller will send the data directly; in this case a strain warning message is emitted by the patient monitor. The patient can decrease his heart rate and the frequency of the heart support of the muscles by reducing his physical activity.

Pulse saving mode

If the average stimulation frequency is in a region in the vicinity of the upper limit value, the automatic pulse saving mode can operate when it is activated by the doctor and/or the bearer of the implant. At low activity, in this mode the stimulation pulse is so distributed within the stimulation burst, that initially an adequate pulse number is generated for a muscle contraction, but during the following progress of the stimulation one to two pulses can be saved by stretching, i.e. reducing the stimulation frequency. This reduces the number of the applied pulses and consequently the average stimulation frequency. During phases of high activity the mechanism does not operate for reasons of safety.

25

Region 2:

Patient monitoring and communication unit

The second region of the muscle pacemaker serves the purpose of monitoring the patients, recording and storing the measured data and telemetric communication with the surrounds.

30

Real-time patient monitoring

The real-time patient monitoring allows the treating doctor to have an overview of the momentary physiological data, like ECG, EMG and blood pressure. For this purpose, after activating the measuring module, the data are recorded, digitalised
5 and presented compressed via a wireless connection from the implanted device via the respective electrodes (ECG and heart rhythm: heart sensing electrode; EMG: stimulation electrodes) and sensors (absolute pressure sensor). The data is graphically illustrated and is logged in on the receiving monitoring unit (patient monitor). A possibility to connect the patient monitor to a telecommunication path,
10 like for example a telephone line, allows a remote diagnostic monitoring of the patients.

Recording and storing "long-term" physiological data

The monitoring unit of the muscle pacemaker records at cyclical intervals
15 (adjustable from 1 min to 1 h) the heart rate and the systolic as well as diastolic blood pressure. This data is stored tabulated in the pacemaker and a trend analysis is carried out. In a routine case the stored tabulated values are transferred once a day to the monitoring unit, that transmits this to the treating doctor, for example, by telephone line. If, however, the trend analysis reveals a
20 life-threatening risk to the patient, the result of the analysis is immediately transmitted telemetrically to the monitoring unit. If the limit values, determined by the treating doctor, are exceeded, the monitoring unit informs the treating doctor or an emergency centre and transmits via a wireless radio connection (UMTS/GSM) the patient data as well as the GPS position of the patient.

25

Programmability of the muscle pacemaker

For the purpose of modification of the existing stimulation pattern and activation/deactivation of various operating modes, the implanted device has to react to external requests. For this reason the telemetry component and the
30 microcontroller 2 are in receiving position at cyclical intervals (adjustable from seconds to several hours).

The following parameters of the stimulation pattern can be reprogrammed:

- stimulation voltage,

- stimulation phase
- temporal distribution of the stimulation pulse,
- type and frequency of the support modes,
- delay period to R-wave,
- 5 • duration of day and night rhythm and labour and rest rhythm,
- position of electrodes.

The following operating modes can be activated and deactivated:

- day and night rhythm and labour and rest rhythm,
- 10 • pulse saving mode,
- measured data recording in real-time,
- pacemaker diagnosis program,
- measuring the impedance of the stimulation electrodes,
- measuring battery voltage.

15

The patient monitor (monitoring unit) is a battery-operated system that can be carried by the patient.

It serves the purpose of

- 20 • self-control of the patient to obtain the average stimulation frequency in the range of 0.2 Hz-2 Hz, in particular 0.7 Hz-1 Hz, for example per 24 h, while a coloured light indicator (green, yellow, red) signals the average stimulation frequency realised at cyclical intervals;
- telemonitoring the patient by the treating doctor, whereby the physiological real-
25 time and long-term data recorded by the implant is telemetrically received, logged in and further conveyed. The further conveying of the data is carried out either over the integrated telephone modem or by means of wireless data in a radio network, e.g. UMTS/GSM network;
- determining the position of the patient in emergency situations by an integrated
30 GPS receiver;
- as a programming device for basic stimulation parameters and operating modes, that can be set by the patient himself.

The patient monitor comprises a microcontroller, a telemetry module, a standard GPS receiver, a standard modem component as well as a UMTS/GSM module.

5 To visualise the average stimulation frequency and to report the status of the system, the patient monitor is fitted with a graphic display as well as luminescent means, in particular a light emitting diode display. The data input is carried out menu-controlled by means of pushbuttons. As an alternative an input by a pointer is possible.

10 Fig.2 shows a device for muscle stimulation with a pulse generator unit 9 to generate and emit an electric stimulation pulse, a control unit 10 to control the pulse generator unit 9, to adjust the amplitude and frequency of the stimulation pulse and to ensure that the stimulation pulses are delivered to a muscle to be stimulated. Furthermore, a detection unit 11 is provided to detect the momentary,
15 spontaneous or stimulated heart rhythm of the bearer of the device. These basic components of the device according to the invention for muscle stimulation are accommodated in a common housing 12. In addition, a counting unit 13 and a memory unit 14, to count and store the number of stimulation pulses delivered within a definable period, are also situated in the housing. The determination unit
20 15, also provided, serves the purpose of determining an average stimulation frequency within a definable period of time. Finally, a pulse saving means 16 with a calculating unit 17 is provided in the housing 12. The calculating unit 17 serves the purpose of calculating a stimulation pattern according to an equation, that determines the stimulation pattern as a function of the average stimulation
25 frequency.

The embodiment of Fig.3 differs from that of Fig.2 by that two spatially separated housings 12, 18 are provided. The housing 12 with the pulse generating unit 9, the control unit 10 and detection unit 11, including a transmission and reception
30 unit 19 to communicate with the components in the other housing 18, is provided to be implanted in the body of a patient. In this embodiment the counting unit 13, the memory unit 14, the determination unit 15 as well as the pulse saving means 16 are arranged spatially separated from the implanted housing 12. The communication is carried out in a wireless manner by means of the transmission

and reception unit 19 and the transmission device 20, allocated to the respective housings 12, 18.

With regard to the extracorporeally provided housing 18, the embodiment of Fig.4
5 is complemented by further components. A memory module 21 to store the temporal progress of the number of delivered stimulation pulses is additionally provided in the housing 18, as well as an analysing unit 22 to determine as to how often and when certain limit values of a heart rate and/or of the average stimulation frequency were exceeded or not reached. These components are
10 drawn in dash-dot lines and can be optionally also provided directly in the implanted housing 12. Therefore in the illustration of Fig.4 they are drawn in dash-dot lines adjacent to the housing 12. Because in the embodiment according to Fig.4 essential functional components of the device according to the invention are provided extracorporeally in housing 18, this sub-assembly can act as a
15 monitoring unit 23. In the monitoring unit 23 a programming unit 24 is provided, while programmable commands are conveyed to the control unit 10 in the housing 12 via the transmission device 20 and the transmission and reception unit 19. In this embodiment the monitoring unit 23 further comprises means 25 to transmit and receive positional data as well as means 26 to transmit and receive
20 wireless signals to transmit physiological data of the patient to a display and evaluating unit of a receiver. The monitoring unit 23 has optical and/or acoustical and/or tactile indicating means (not illustrated in detail) to illustrate the average stimulation frequency.

List of reference numerals:

	1	Microcontroller
	2	Microcontroller
5	3	Analogue/digital converter
	4	Analogue/digital converter
	5	Telemetry unit
	6	Pressure logics
	7	Serial interface
10	8	R-wave unit
	9	Pulse generator unit
	10	Control unit
	11	Detection unit
	12	Housing
15	13	Counting unit
	14	Memory unit
	15	Determination unit
	16	Pulse saving unit
	17	Calculating unit
20	18	Housing
	19	Transmission and reception unit
	20	Transfer device
	21	Memory module
	22	Analysing unit
25	23	Monitoring unit
	24	Programming unit
	25	Means to transmit and receive positional data
	26	Means to transmit and receive wireless signals
	D	Pressure data
30	P	Serial high-speed connection
	R	Trigger signal
	S	Stimulation pulse

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CLAIMS:

1. A device to induce muscle contractions of a muscularly driven heart support system, that operates parallel to or in series with a diseased heart, comprising:

- 5 • a pulse generating unit to produce and emit an electrical stimulation pulse;
- a control unit to control the pulse generating unit to adjust the amplitude and frequency of the stimulation pulse and to ensure that the stimulation pulses are delivered to a muscle to be stimulated;
- 10 • a detection unit to detect the momentary, spontaneous or stimulated heart rhythm of the bearer of the device;
- a housing, in which the pulse generator unit, the control unit and the detection unit are accommodated;
- a memory module to store the temporal progress of the number of
- 15 stimulation pulses delivered within a definable period of time, as well as
- a counting unit and a memory unit to count and store the number of stimulation pulses delivered within a definable period are provided, while the stimulation pulses are grouped into modifiable stimulation bursts, wherein
- a determination unit to determine an arithmetically averaged
- 20 (average) stimulation frequency within the definable period of time, while the average stimulation frequency is the quotient of the stimulation pulses of the modifiable stimulation bursts stored by the memory unit and delivered within the defined period of time and of the defined period of time, in which the stimulation pulses were counted and stored,
- 25 • wherein a continuously operating evaluation unit is provided to adhere to the limit values for the average stimulation frequency,

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- wherein pulse saving means are provided to reduce the average stimulation frequency depending on the maximum average stimulation frequency determined by the evaluation unit,

- wherein the pulse saving means comprise a calculating unit to
5 calculate a stimulation pattern according to an equation, that determines the stimulation pattern depending on the average stimulation frequency, while the number of stimulation pulses per stimulation burst is variable to reduce the average stimulation frequency,

- wherein a monitoring unit, carried extracorporeally by the patient, is
10 provided to illustrate the average stimulation frequency and for self-control of the patient, and

- wherein the limit values for the average stimulation frequency are individually adjustable in a range of 0.2 stimulation pulses/sec up to 2 stimulation pulses/sec.

15 2. A device according to claim 1, comprising means for the program-controlled transmission of the average stimulation frequency from the determination unit to the calculating unit.

3. A device according to claim 1 or 2, comprising an analysis unit to
20 determine as to how often and when established limit values of at least one of heart rate and the average stimulation frequency are exceeded or not reached.

4. A device according to any one of claims 1 to 3, characterised in that the counting unit and the memory unit are accommodated in the housing.

5. A device according to claim 4, characterised in that at least one of the determination unit and the pulse saving means is integrated in the housing
25 that accommodates the control unit.

6. A device according to claim 5, characterised in that at least one of the memory module and the analysing unit is integrated in the housing that accommodates the control unit.

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7. A device according to any one of claims 1 to 6, characterised in that the monitoring unit has a programming device to produce a programming signal and a transfer device to transfer the programming signal to a transmission and reception unit in the housing, accommodating the control unit.

5 8. A device according to any one of claims 1 to 7, characterised in that at least one of the counting unit, the memory unit, the determination unit, the pulse saving means, the memory module and the analysing unit is a component of a monitoring unit that is at least one of stationary and is extracorporeally carried by the bearer.

10 9. A device according to any one of claims 1 to 8, wherein the at least one of average stimulation frequency and a magnitude range, into which the average stimulation frequency falls, can be illustrated on the monitoring unit at least one of optically, acoustically and in a tactile manner via indicating means.

10. A device according to any one of claims 1 to 9, characterised in that
15 the monitoring unit comprises means to transmit and receive positional data.

11. A device according to any one of claims 1 to 10, characterised in that the monitoring unit comprises means to transmit and receive wireless signals to transmit physiological data of the patient to a display and evaluating unit of a receiver.

20 12. A device according to any one of claims 1 to 11, characterised in that biphased stimulation pulses can be emitted by the pulse generating unit.

13. A device according to any one of claims 1 to 12, characterised in that an energy storage in the housing can be transcutaneously charged.

14. A device according to any one of claims 1 to 13, characterised in
25 that the definable period of time is at least 30 minutes.

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15. A device according to any one of claims 1 to 14, characterised in that the definable period of time is at least 12 hours.

16. A device according to any one of claims 1 to 15, characterised in that the definable period of time is at least 24 hours.

17. A device according to any one of claims 1 to 16, characterised in that the amplitudes of the stimulation pulses are variable within a stimulation burst.

5 18. A device according to any one of claims 1 to 17, characterised in that the pulse widths of the stimulation pulses are variable within a stimulation burst.

19. A device according to any one of claims 1 to 18, characterised in that the pulse interval between two stimulation pulses are variable within a stimulation burst.

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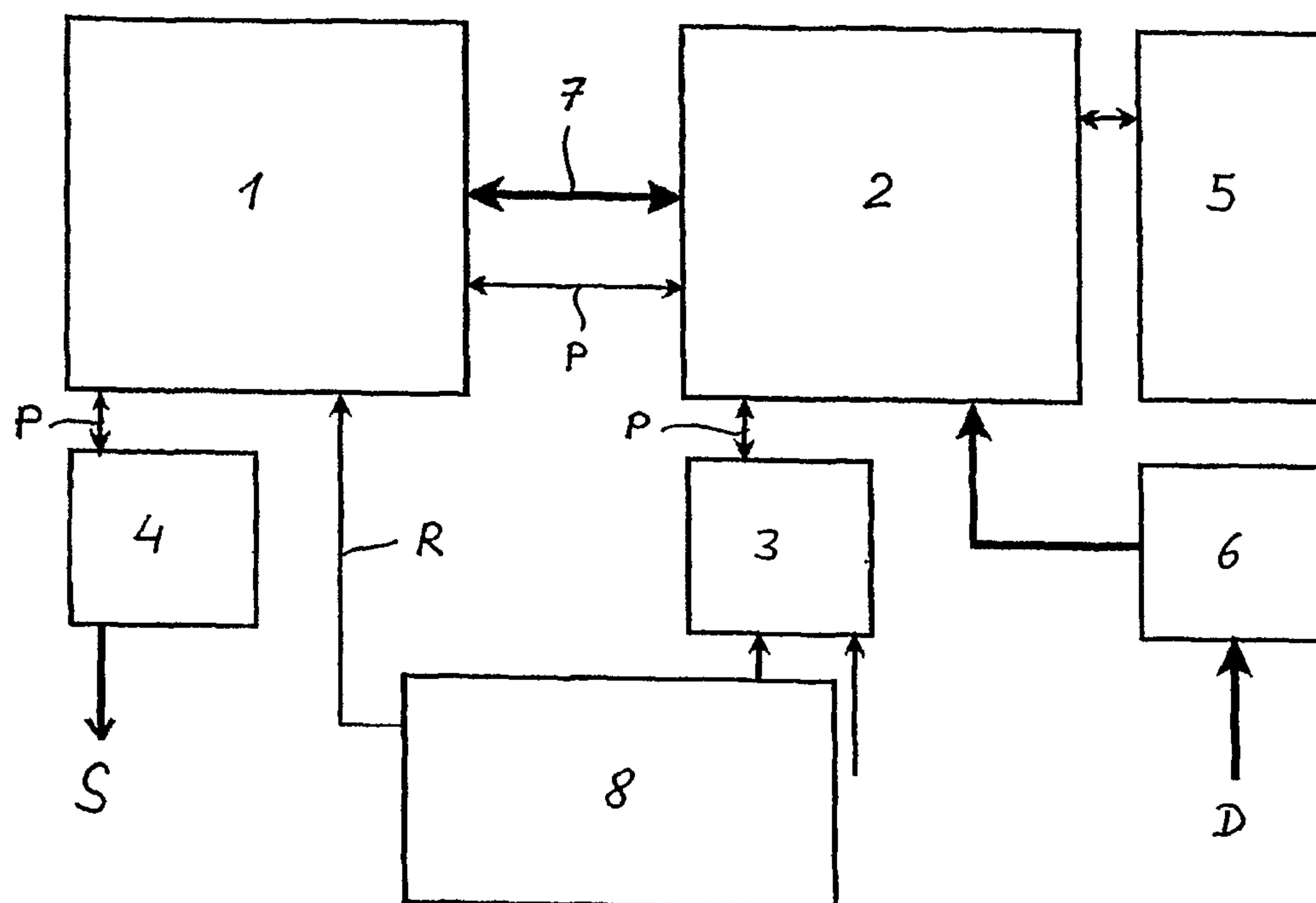


Fig. 1

